Hjelt Institute, Department of Public Health, University of Helsinki
Kuopio University Hospital, Unit of Primary Health Care
Finland

PEER FACILITATION AND MULTIFACETED INTERVENTION IN GUIDELINE IMPLEMENTATION –

ENHANCING CARE OF CARDIOVASCULAR DISEASES IN PRIMARY CARE

Raija Sipilä

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Supervised by
Professor Esko Kumpusalo, MD, PhD
Kuopio University Hospital, Unit of Primary Health Care
Kuopio, Finland

and

Medical Director Eeva Ketola, MD, PhD
Helsinki City Health Department
Helsinki, Finland

Reviewed by
Docent Ulla Rajala, MD, PhD
Institute of Health Sciences
University of Oulu
Oulu, Finland

and

Docent Seppo Miilunpalo, MD, PhD
School of Health Sciences
University of Tampere
Tampere, Finland

Dissertation opponent
Professor Pekka Honkanen, MD, PhD
Institute of Health Sciences
University of Oulu
Oulu, Finland

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ABSTRACT

Clinical practices are not sufficiently in line with current evidence compiled in evidence based guidelines. Changing practice behaviour is challenging. Therefore active, tailored and often local interventions are needed to lead these changes.

The aims of the present study were to describe a local, practical and comprehensive multifaceted guideline implementation intervention, assess the feasibility of the intervention and its effects on care processes. The second aim was to approximate the time resources needed for preventive activities. The third aim was at patient level to evaluate long-term effects of an individualised lifestyle intervention on cardiovascular risk factor levels.

The key components of the two-year intervention were internal pair facilitation, education and consensus meetings, local guideline development, audit and feedback, and marketing. The feasibility of the intervention, and structure and process changes were measured with questionnaires and clinical audit recordings during appointments (BP measurements, diabetes and dyslipidaemia patients). National Prescription register data was used to evaluate changes in antihypertensive drug prescribing and chart audits to assess long-term clinical outcomes.

For different patient groups changes in the division of tasks had been made at 22–29 of 31 practices, different local guidelines were adopted at 22–31 practices and self-measurement sites were set up for all practices. BP measurements were reduced and targeted at those with poor treatment balance. Using modelling the time allocations by nurses for BP measurements and lifestyle counselling were reduced from 11.9% to 6.3% of their total working time. No statistical changes between intervention and control GPs were detected in time in antihypertensive prescribing. The main advantages of the intervention were mutual clinical practices and clarified professional roles. The main barrier to change was time constrains.

In conclusion, internal facilitation is a feasible way of promoting changes in care processes in primary care. However, support and leadership are needed to adopt systematic and sustained quality improvement (QI). Multiprofessionality is important in QI initiatives in primary care, but some practices, such as prescribing, need more individualised interventions.

TIIVISTELMÄ

Kliiniset toimintatavat eivät riittävästi vastaa nykyisiä näyttöön perustuvia hoitosuosituksia. Muutoksen läpivienti on haastavaa. Siksi tarvitaankin aktiivisia, räätälöityjä ja usein paikallisia interventioita muutoksen aikaansaamiseksi.

Tämän tutkimuksen tavoitteena oli kuvata paikallinen, käytännöllinen ja kattava monitekijäinen hoitosuositusten käyttöönottointerventio sekä arvioida intervention käyttökelpoisuutta ja vaikutuksia hoitoprosesseihin. Toisena tavoitteena oli arvioida preventiiviseen työhön tarvittavaa työaikaa. Kolmantena tavoitteena oli arvioida henkilökohtaisen elintapaintervention pitkäaikaisvaikutuksia sydän- ja verisuonitautien riskitekijöihin.

Intervention keskeiset osatekijät olivat sisäinen parifasilitointi, koulutus ja konsensuskokoukset, paikalliset hoitosuositukset, auditointi ja palaute sekä markkinointi. Intervention käyttökelpoisuutta, sekä muutoksia rakenteissa ja prosesseissa tutkittiin kyselyillä sekä vastaanoton yhteydessä kirjatuilla kliinisillä auditoinneilla (verenpaineen mittaaminen, diabetes ja dyslipidemia potilaat). Muutoksia verenpainelääkkeiden määräämisessä tutkittiin kansallisesta reseptirekisteristä haetuilla tiedoilla ja pitkäaikaisia kliinisiä tulosmuuttujia potilaskertomusauditoinnilla.

Eri potilasryhmien hoidon työnjaossa tehtiin muutoksia 22–29 terveysasemalla, aiheesta riippuen paikalliset hoitosuositukset otettiin käyttöön 22–31 asemalla ja itsemittauspisteet perustettiin kaikille 31 asemalle. Verenpainemittaukset vähenivät ja kohdistuivat huonossa hoitotasapainossa oleviin potilaisiin. Mallinnuksessa hoitajien verenpainemittauksiin ja elintapaneuvontaan tarvitsema aika väheni 11,9 %:sta 6,3 %:iin kokonaistyöajasta. Interventio- ja kontrolliryhmän välillä ei havaittu tilastollisesti merkitseviä eroja verenpainelääkkeiden määräämisessä. Intervention pääasialliset edut olivat yhteiset toimintakäytännöt ja selkeytyneet ammatilliset roolit. Suurin este muutokselle oli aikapula.

Yhteenvetona voidaan todeta, että sisäinen fasilitointi on käyttökelpoinen tapa edistää muutoksia perusterveydenhuollon toiminnassa. Järjestelmällinen ja kestävä laatutyö vaativat kuitenkin tukea ja johtajuutta. Moniammatillisuus on tärkeätä perusterveydenhuollon laatutyössä, mutta joidenkin toimintatapojen, kuten lääkkeenmääräämisen, muutos vaatii henkilökohtaisempia interventioita.

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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications which are referred to in the text by the Roman numerals I – IV:

I Sipilä R, Ketola E, Tala T, Kumpusalo E. Facilitating as a guidelines implementation tool to target resources for high risk patients – the Helsinki Prevention Programme (HPP). J Interprof Care 2008;22:31–44.

II Sipilä R, Ketola E, Tala T, Klockars M. Evidence in action – guidelines directing workload. Qual Saf Health Care 2010;19:514–8. Epub 2010 Apr 3.

III Sipilä R, Helin-Salmivaara A, Korhonen MJ, Ketola E. Change in antihypertensive drug prescribing after guideline implementation: A controlled before and after study. BMC Fam Pract 2011; 12:87. doi: 10.1186/1471-2296-12-87.

IV Sipilä R, Ketola E. Multifactorial intervention on cardiovascular risk levels in primary care – An eight year follow-up. Submitted

In addition, some previously unpublished data are presented.

ABBREVIATIONS

ACE	Angiotensin converting enzyme
AGREE	The Appraisal of Guidelines, Research and Evaluation
ARB	Angiotensin receptor blocker
ATC	Anatomical Therapeutic Chemical
BBA	Beta-blocking agent
BMI	Body mass index
BP	Blood pressure
CC	Current Care
CCB	Calcium channel blocker
CDSS	Clinical decision support systems
CHD	Coronary heart disease
CI	Confidence interval
CME	Continuing medical education
CV	Cardiovascular
CVD	Cardiovascular diseases
EBM	Evidence based medicine
EBMeDS	Evidence-Based Medicine electronic Decision Support
EOV	Educational outreach visit
EPR	Electronic patient records
GP	General practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
PCP	Primary care practice
QI	Quality improvement
QOF	Quality and Outcome Framework
RAAS	Renin-aldosterone-angiotensin system
RCT	Randomised controlled trial
SII	Social Insurance Institution
[ ]	References published in scientific publications, reports and books
( )	Other references such as web sites and personal communications

1. INTRODUCTION

Changing clinical practices has proven to be challenging. Implementation of new practices in health care often requires changes at least at the organisational and professional levels. Different barriers, however, hinder these changes. These barriers can be related to socio-political context, organisation, professionals, and innovation it-self [79]. Despite the challenges, the need to adopt new practices is inevitable due to changes in society, the structures of health care and clinical knowledge.

Indeed, a large body of new scientific knowledge is published yearly. Clinical practice guidelines are frequently developed to facilitate the adoption of this knowledge at the professional level. In these guidelines knowledge of one disease is critically reviewed and compiled, the ultimate aim being to improve quality of care and patient outcomes [141, 264]. However, publication and distribution is not enough, active strategies are needed to implement the guidelines in daily practice. Local adoption has often been suggested because no intervention is effective under all circumstances but most are effective under certain circumstances [109, 113]. Therefore setting, target group and special barriers should be considered when planning implementation interventions.

Quality improvement (QI) aims to improve health care quality and outcomes through local initiatives [62, 111, 185]. According to WHOs description, health care is of high quality if it is safe, effective, patient-centred, timely, equitable, and efficient [295]. Because the aims are fairly parallel with the aims of guidelines and local adoption is needed, guideline implementation is often embedded in QI initiatives. Furthermore, due to local settings the methods of these programmes have not been as rigorous as in purely scientific research [62, 111, 185]. It has been argued that QI is an essential part of good clinical practice where data guide improvements, and it is therefore different from human subject research [185]. However, in recent years QI projects have more often used research methods and tried to produce information that is useful beyond local settings [111].

This study is an evaluation of a practical QI programme that arouse from needs of one primary care organisation to improve prevention and treatment of cardiovascular diseases (CVD), a disease group which significantly burdens primary care resources. Cardiovascular diseases are the leading cause of death both in the world and in Europe [294]. Although in most of Europe CVD death rates have been falling, still nearly half of all European deaths are due to these diseases [8]. Mortality is highest in Eastern Europe followed by the central part with Finland even though the decrease in death rates has been rapid. In one decade in Finland

death rates fell by approximately 35%. However, the risk factor levels are still not optimal and there is still room for improvements [225].

At the health care provider level it is easiest to influence one's own professional and organisational practices, and of course to some extent the patients attitudes and actions. At the time of the planning the intervention it seemed that multifaceted interventions would be most effective [15, 110]. Therefore a multifaceted intrinsic pair facilitation intervention was designed to enhance chronic diseases care. The modus operandi of the intervention was mainly organisational and process oriented with an aim to introduce new ways of task sharing, recognition of CVD patients and implementation of evidence based guidelines and treatment practices. The present study aims firstly to evaluate by audits, questionnaires and register data the structural and process changes accomplished during the intervention. Secondly, at the level of organisation, the effect on the workload of those involved was approximated. Furthermore one part of this thesis deals with the long-term effects of a patient-oriented individual intervention.

2. REVIEW OF THE LITERATURE

2.1 Primary care in Finland

Finland with a population of 5.4 million (1) is divided into five administrative areas and further into smaller municipalities. The number of the municipalities has little by little diminished due to federations to the present 336 (2011). The population of the municipalities varies from approximately 588 500 (Helsinki) to 119 (Sottunga), the median being 5850 (2).

Characteristic for Finnish health care is multichannel financing (mainly by taxes), organisation responsibility of municipalities, government steering, and preventive work. Health care is organised at different levels: secondary care at the hospital districts level, primary care in municipalities, occupational health care, private health care, pharmacies and social services.

The Primary Health Care Act (1972) states that every municipality must have a health centre that provides primary health services. They may provide services themselves, in co-operation with neighbouring municipalities or purchase them from private service providers. Only certain services are defined by law (such as primary medical care, a variety of preventive services, home nursing, family planning, dental care, and environmental health services) and therefore primary health services may differ from one health centre to another [275]. As in other European countries general practitioners (GP) are the gatekeepers of the system [275]. If needed, a GP can refer a patient to secondary care in the hospital district. The coverage of primary care varies being lowest in bigger cities. At least two structures explain this variation. Especially in major cities, private services provide a significant proportion of outpatient care. Furthermore preventive occupational health care services are obligatory and some employers provide supplementary outpatient services. Thus occupational health care is an important part of primary care [159].

The comprehensive network of health centres was made up of 172 centres in 2010 (3). The administrative unit, health centre, can consist of several group practices, i.e. primary care practices. Two different systems to organize the services are used. In the conventional system the appointments are made to any available physician in the health centre. In the 1980's a new system, the "personal doctor", was introduced where a person or a family is assigned to one health centre doctor, usually on geographical grounds. A doctor is responsible for a population of 1600–2500. Municipalities have had the freedom to choose between the two systems; approximately half the physicians working in health centres belong to the personal doctor system [275] (4). A new Health Care Act, however, entered into force on 1 May 2011. The reform is intended to improve the status of patients, by giving them

freedom to choose the place of care, and improving the quality of care [208]. This change will probably enhance the use a modified "personal doctor" –model, the so called list-model. In this model patients with chronic diseases and children can register on the patient list of a certain doctor.

In addition to group practices, characteristic to Finnish primary care are the multiprofessional teams serving the population. Besides nurses, for example physiotherapists and dieticians can participate in patient care. Nurses have had a strong position in Finnish primary care as independent professionals of preventive services such as those found in maternity clinics, child health clinics, school health care and vaccination services [275]. In recent years nurses have been taking more responsibility for the care of chronic diseases [224]. This has not only strengthened the team work between doctors and nurses but also increases the need for collaborative education and development.

2.1.1 Challenges

In Finland, as in other countries, the primary care has faced several challenges in the past few years [208, 275]. The main challenges have been difficulties in access to care, an unclear mission, system-centeredness, and recruitment problems. The shortage of GPs led to a new trend: the outsourcing of the physician workforce. Especially young medical graduates have worked for medical staffing agencies [207, 275]. In 2010 13% of physicians working in primary care were employed by these companies (5). Overall the shortage of health centre physicians diminished in 2010 (by an average of 6%) and the rise in outsourcing ceased (3,5).

Several actions have been taken to solve these problems. To tackle poor access to care, the ministry of health ruled by law national standards for access to health services and introduced a waiting time guarantee in 2005. Furthermore a national action programme for primary care, consisting of 24 actions, was launched in 2008 [208]. The programme, together with the new Health Care Act, aims at clarifying the mission of primary care and at strengthening the patient's role. The implementation of the Chronic Care Model [20, 21] was chosen as the main tool and numerous local and regional development projects have been financially supported. In addition national recruiting portals have been launched and changes in division of responsibilities between health professionals are supported. Apart from implementation of the Chronic Care Model a limited nurse prescribing remodels the division of tasks in primary care. The quality of care is supported by electronic solutions, such as the development of a national electronic patient record system (ongoing since 2006) and the use of electronic decision support system. As a result of the response to challenges described above and possibly due to various other actions, visits to GPs have steadily decreased from the year 2000 until 2010 while visits to other health care professionals have increased (6).

2.2 Cardiovascular diseases

In Finland the leading cause of death is cardiovascular diseases (CVD), especially ischemic heart disease, which have been the cause of over one fifth of Finnish deaths. For the working age population alcohol diseases overtook CVDs as the leading cause of death in 2005 with CVDs still remaining in second place (7).

The risks for CVDs are widely known. The major risk factors are hypertension, dyslipidaemia, type 2 diabetes, metabolic syndrome, obesity, smoking, family history, and male sex. Furthermore diet, physical inactivity, social status and mental health are related to cardiovascular morbidity. More recent findings further suggest that inflammation may be one key pathogenic mechanism behind CVDs [223]. There is strong evidence that major risk factors correlate with cardiovascular (CV) morbidity and mortality [11, 19, 118, 137, 201]. In fact, the Interheart Study confirmed that nine of these common and potentially modifiable risk factors account for over 90% of the risk of an initial acute myocardial infarction: dyslipideamias, hypertension, smoking, diabetes, obesity, low consumption of fruits and vegetables, lack of exercise, alcohol consumption and psychosocial factors [300]. The strongest predictors were current smoking and dyslipidaemia, followed by diabetes and hypertension. This is in line with findings from Euroaspire cohort, where along with previous coronary heart disease (CHD), smoking and diabetes emerged as the strongest predictors for CV mortality [55].

Prevention aims to reduce CV morbidity and mortality by reducing risk factors at the three following levels: population, high risk individuals (primary prevention) and individuals with established CV organ damage or disease (secondary prevention) [105]. Health care policies and community interventions tackle the problem at the population level whereas health care professionals act mainly at the level of individual. At the individual level guidelines emphasize lifestyle interventions; smoking cessation, weight reduction, moderation in alcohol consumption, dietary changes (decreased salt intake, increased fruit and vegetable intake, and low saturated fat intake), and increased physical activity [105, 289–291]. If lifestyle changes do not have a favourable effect or the risks are high, drug treatment is needed.

2.2.1 Assessment of total cardiovascular risk

Despite the clear association between a single risk factor and the relative risk of CVDs the effect on absolute CV risk is minor [142]. Therefore estimation of a patient's absolute total CV risk has been recommended in guidelines at least for a decade instead of treating single risk factors. To illustrate the complexity of risk assessment, Figure 1 shows an example of the risk at three different blood pressure (BP) levels with additional consecutive risks found in the Framingham Heart Study population.

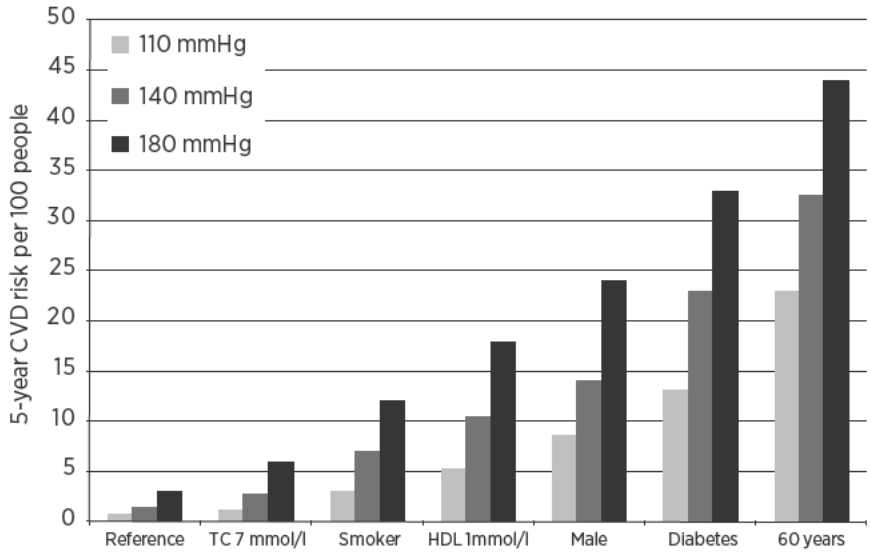

Figure 1. Absolute risk of cardiovascular disease over 5 years in patients with systolic blood pressure at 110, 140 and 180 mmHg at specified levels of other risk factors. The reference category is a 50-year-old female, non-diabetic, non-smoker, with cholesterol of 4.0 mmol/l and HDL of 1.6 mmol/l. In the other categories, additional risk factors are added consecutively. Modified from Jackson et al. 2005 [142]. TC= total cholesterol, HDL= high density lipoprotein.

Nevertheless risk assessment is difficult and both GPs and specialists tend to inflate both the risks and treatment benefits [91]. To help the assessment, a range of CV risk estimation systems are available. These include for example the Framingham system, the SCORE chart, PROCAM, ASSIGN, QRISK, WHO, the UKPDS risk engine, and several regional versions of some of these systems [44, 142]. The aim of these tools is to help to estimate the likelihood of an apparently healthy person developing a CV event or dying in a defined period of time; and through the estimations target preventive actions for those who need active risk management. Those with established CVD, renal diseases, type 2 diabetes or high levels of individual risk factors are automatically considered as a high-risk population [60].

The most used models in Finland are Framingham, SCORE and FINRISK. The SCORE cohort includes the Finnish population [43]. And indeed, ideally the estimation model should be based on cohort studies that include the population for which it is used [44]. A good example of such estimation system is the FINRISK function. It is solely based on the national FINRISK cohort and includes a FINRISK population from 1992, which is not included in the SCORE cohort.

Most risk estimation systems include age, sex, smoking, blood lipids, and blood pressure as core variables although there is some variation. Models with several risk factors tend to be more predictive, but these systems become more complex and

time consuming, and may be less feasible in different regions [44]. Furthermore the ability to separate those who will develop an endpoint from those who will not varies due to different endpoints being evaluated and patient characteristic [155, 273]. For health care professionals the usability increases with a simple lay out and with integrated systems [44]. In addition different quantitative information is helpful for understanding the risk, preferably absolute rather than relative figures should be used [211]. Further physicians have to be cautions about how they interpret risks for patients [120, 134] because overestimation and medicalisation of risk factors may cause unnecessary concerns and harm.

2.2.2 Prevalence of cardiovascular risks

Cardiovascular risk levels have been actively monitored in Finland from 1972 (North Karelia project) in population-based studies at five year intervals [236]. The surveys have been conducted as a part of the WHOMONICA studies (FINMONICA) from 1982 and as national FINRISK studies from 1997 to 2007. The cross-sectional population surveys in three to five regions include a combination of questionnaires and health examinations, including a population aged 25–64 years (25–74 years in 2009).

In the original 1982 FINMONICA population (three areas) the prevalence of hypertension (systolic BP $\geq$140 mmHg or diastolic BP $\geq$90 mmHg or antihypertensive treatment) for men was as high as 68% (women 55%) in the Kuopio area and declined in all areas to approximately 50% (35%) by 2002 [151]. In the two latest surveys (2002 and 2007) elevated blood pressure ($\geq$140 and/or $\geq$90 mmHg) was observed in 39% and 43% of men and 27% and 33% of women [225].

Similarly to hypertension, in the beginning of the 1970's the prevalence of high total cholesterol ($\geq$5 mmol/l) was widespread, over 90% for both men and women [236]. In 2007 the corresponding figure was 58% [225]. The prevalence of obesity has increased steadily from the 1980's. In 2007 29% of the men (women 43%) were overweight (body mass index (BMI) $\geq$ 25 kg/m^2) and 22% (23%) were obese (BMI$\geq$30 kg/m^2) [272]. The prevalence of smoking has declined for men until a new increase in 2002, and has increased for women until a decline in the 2007 survey when the prevalence was 29% and 20% [225, 236, 274].

According to estimations there are half a million diabetics in Finland; most of who are type 2 diabetics [72]. In the 2007 FINRISK population, 7% of men (women 6%) reported to have diabetes or at least once measured elevated blood glucose [225]. These figures are similar to another population-based cohort where 7% of the men (4%) were previously diagnosed diabetics [226]. When taking into account previously undetected diabetics, the prevalence was 16% (11%), respectively. These figures doubled further when those with impaired glucose tolerance were considered.

In these population based surveys variations between regions have been observed. The levels of hypertension, hypercholesterolaemia and smoking (for men) have declined markedly from the beginning of 1970's though the decline for hypertension seemed to have levelled off like serum total cholesterol levels earlier (Table I). The prevalence of obesity has been steadily increasing. This decline in the major cardiovascular risks has been reflected in CV mortality which has dramatically decreased [272].

Table I. The development of mean levels on CV risk factors in Finland (male/female) for the 25 to 64 year-old population.

Study and year	Sample size	SBP (mmHg)	DBP (mmHg)	Total cholesterol (mmol/l)	BMI (kg/m^2)	Smoking (%)
FINMONICA 1982*	11395	144 / 139	86 / 82	6.14 / 6.07	26.3 / 25.9	40 / 18
FINMONICA 1987*	7932	142 / 137	87 / 82	6.12 / 5.96	26.8 / 26.3	36 / 17
FINRISKI 1992**	7927	139 /133	84 / 79	5.76 / 5.54	26.7 / 25.8	35 / 21
FINRISKI 1997***	10000	137 / 130	85 / 80	5.54 / 5.46	26.9 / 26.1	32 / 20
FINRISKI 2002***	9952	136 /130	82 / 77	5.61 / 5.43	27.1 / 26.3	34 / 23
FINRISKI 2007***	7963	136 /129	82 / 76	5.29 / 5.19	27.2 / 26.4	29 / 20

The survey has been conducted in *three regions, ** four regions, and *** five regions. SBP = systolic blood pressure, DBP = diastolic blood pressure, BMI = body mass index. The figures have been collected from Vartiainen et al. 2008 [272]

From worldwide perspective according to a systematic review (1980–2003) the prevalence of hypertension varies widely; in rural India for men being as low as 3.4% to as high as 72.5% in Poland for women [153]. The prevalence is high in Germany, Spain and Finland (40–60%) compared to rest of the Western Europe (30–40%), and it is even lower in North America (<30%) [153, 287]. The prevalence of diabetes in Europe in the adult population has been estimated to be 8.5% in 2010 with large variations between countries (from 2 to 12%) [139]. In population-based studies the prevalence of hypercholesterolaemia has varied from 30 to 59% [76, 199]. The estimation of the world's overweight adult population for 2005 was 23% and for the obese population 10%, in Western Europe 40% and 20%, respectively [154].

The Euroaspire study group has surveyed the CV risk factor levels and treatment levels at three time points for patients with clinical CHD in nine to 22 countries [167]. Risk factor levels are high, considerable variation between countries exist and the documentation is poor. In the comparison of these three cohorts (1995–2007) the percentage of patients that smoke and have elevated BP has remained unchanged: obesity and self-reported diabetes have increased, while the percentage with elevated total cholesterol has diminished [167].

2.2.3 Treatment results of risk factors

From the 1980's the proportion of Finns with hypertension who were aware of their hypertension, and who were both aware and controlled has steadily risen although the overall risk factor control is still poor [150, 151]. In the last FINRISK survey (2007) up to 45% of hypertensives were treated [150]. Of these further 25 to 53% were adequately controlled depending on sex and area. The treatment levels of high-risk patients and patients with CHD in Finland in primary care are collected in Table II. From 20 to 30% of patients reach their target blood pressure although the percentage is higher when the patients have established CHD. The percentage of patients reaching target levels for hypercholesterolemia varies greatly due to the different targets set.

The treatment of hypertension and hypercholesterolemia has been more active in North America than in Europe and treatment levels are better [281, 287]. The results have improved from the 1990's; in 2004 in the United States 65% of drug treated hypertensives were controlled compared to 31–46% in five European countries [281]. Antihypertensive or lipid lowering drug treatments given to subjects in the 2006–2007 Euroaspire cohort succeeded in controlling half of the cases [168]. In primary care the corresponding figures were 32% and 46% [167]. The results were considerably lower for diabetic populations and of these 40% achieved the HbA1c goal.

Table II. Percentage of patients with specific risk factor levels in Finland in primary care.

Ref.	Year	Population: N (% male), description, mean age	BP <140/85 mmHg	BMI <30 kg/m²	S-Chol <5.0	Smoking prevalence	DM, HbA1c<7.0%
Meriranta et. al. 2004 * Meriranta 2009 [194, 195]	2002	1130 (46.7), hypertension with drug treatment, 64	22 / 26	66 / 60		11 / 8	21/14
Varis et al. 2008 [270]	2006	718 (50.0), hypertension with drug treatment, 59	23	62	50	14	
Koskela et al. 2011** [164]	2008–2009	161, high risk for CHD 264, CHD	41 27		19 65	65 56	
Winell et al. 2011*** [285]	2010	4886, elevated blood pressure 1203, chronic heart disease 5971, diabetes	45 52 53		63 71 68	13 12 15	 68

BMI = body mass index, BP = blood pressure, CHD = coronary heart disease, DM = diabetes mellitus, N = number, S-Chol = total cholesterol.

* Figures male/female, ** Solely systolic blood pressure, S-Chol<4.5 mmol/l, percentage of those with smoking data, *** Solely systolic blood pressure, LDL cholesterol <3.0 for hypertensives and <2.6 for diabetics and CHD patients, daily smoking

2.2.4 Treatment principles of risk factors

As discussed earlier modification of CV risk factors includes both lifestyle changes and drug treatment. There is little data, or it has been collected using questionnaires, on how the lifestyle interventions were implemented in real life. In her thesis, Meriranta studied the lifestyle interventions discussed at 1130 drug treated hypertensive patients' encounters [194]. Patients reported that increasing physical activity, increasing use of fibres and fruits, diminishing salt intake, and low total fats intake were discussed in 80–90% of encounters whereas the need for weight loss and smoking cessation (for those still smoking) approximately in three out of four encounters. Over 80% reported having made dietary changes, 60% increased exercise and over half lost weight. The patient records do not support these findings. In the EPA Cardio study counselling on exercise was reported for 30% of high-risk patients and diet counselling for 40% [164]. However, both these data collecting methods have biases and it is difficult to collect valid data on actual counselling. Population level lifestyles have changed favourably in Finland [225].

Drug treatment has been studied more extensively both from patient data [169, 195, 270] and from registries [2, 3, 239, 278, 279]. In Finland overall CV drug use has increased [75]. The number of persons entitled to Special Refund for antihypertensive medication was over half a million in 2009. The respective figures for CHD, diabetes and dyslipidemia associated to CHD were192 000, 212 000, and 104 000, respectively. Indeed, chronic hypertension is the most common disease that entitles individuals to a Special Refund. The number of these patients has increased steadily with over 7 000 persons in the twenty-first century. Similar trend for antihypertensive drugs was shown for two cohorts of CHD and diabetes patients [2, 3] and it seems that more intensive treatment with two or more drugs taken concomitantly is more common (Table III). Moreover beta-blocking agents have been the most used antihypertensives though use of agents acting on rennin-angiotensin-aldosterone system (RAAS) has increased rapidly especially for diabetic patients.

There is large variation in use of antihypertensive agents in Europe [89, 259, 280]. A strong tradition has kept the prescription of beta-blocking agents (BBA) high in Finland and in neighbouring Sweden [89, 251] whereas in Norway newer drug classes are introduced more rapidly into daily practice [89]. In a European comparison the United Kingdom seems to be in the opposite, conservative, end of the prescribing spectrum. Use of agents acting on RAAS has increased more rapidly in other regions of Europe, and this drug group is mainly the most frequently prescribed antihypertensives [165, 166]. In North America long-term trends show a decline in use of calcium channel blockers (CCB) [186, 256]. Secondly, the use of agents acting on RAAS has increased from the 1990's, first due to angiotensin-converting enzyme (ACE) inhibitors and lately due to the use of angiotensin receptor

II blockers (ARB). Thirdly, the use of diuretics declined in the late 1990's and increased thereafter. The use of beta-blocking agents has been low compared to Europe but remained stable. In Europe the proportion of patients in monotherapy varies from 40 to 66% [280]. In North America drug treatment is more intensive; only one-third of patients being on monotherapy.

Table III. Treatment practices in Finland, percentage of patients having two or more drugs and specific drugs

Reference	Year	Population	≥2 drugs	BBAs	Diuretic	RAAS	CCBs
National Prescription register							
Wallenius et al. 1996* [279]	1993	279435 patients with antihypertensive drug prescriptions	41	30	27	20	22
Reunanen et al. 2000 [239]	1995	68517 type 2 diabetics		32	40	28	25
Ahola et al. 2009 [3]	2000	80428 diabetics with antihypertensive drug	63	52	50	53	30
Ahola et al. 2009[3]	2006	123111 diabetics with antihypertensive drug	70	55	53	70	33
Ahola et al 2010** [2]	2000	54838 patients with CHD and hypertension (reimbursement)	70	80	28	26	28
Ahola et al 2010** [2]	2006	66141 patients with CHD and hypertension (reimbursement)	79	79	42	43	29
During appointment at primary care							
Kumpusalo et al. 1997 [169]	1995	4294 hypertension patients in 30 PCPs	52	50	45	35	33
Meriranta et al. 2004*** [195]	2002	1130 hypertension patients with drug treatment in 22 PCPs	63	69	39	54	32
Varis et al. 2008**** [270]	2006	718 hypertensive patients with drug treatment in primary care	63	47	43	31/43	32

PCP= primary care practice; BBA=beta-blocking agent; RAAS= agents acting on rennin-angiotensin-aldosterone system; CCB=calcium channel blockers.

*percentages are from total number of prescriptions. Approximately 66% used CCBs or ACE and 50% BBAs, 27% diuretics of men, 55, 44 and 43% of women; **in the analysis of use of specific drug groups included are those CHD patients with antihypertensive drugs with data on both years 2000 and 2006 (n=88195); *** the figure for BBAs is for male patients; **** RAAS divided into ACE inhibitors /ARBs.

The use of lipid lowering drugs has increased in Europe during the 1990's and 2000's [244, 260, 262]. In Finland the use of lipid lowering drugs increased for diabetic patients between 2000 and 2006 by 19% though only one-third of the patients used them [3]. Similarly for CHD patients the use has increased and was nearly 60% in 2006 [2]. At the population level, already over 10% uses statins [188].

The prevalence for secondary prevention is similar in other European countries [166]. Nordic countries have a problem of low doses at initiation [260].

As the prevalence of diabetes has increased the use of anti-diabetic drugs has increased [148]. In a five-year follow-up the use of insulin remained stable while the use of metformin increased rapidly. Similar changes have been observed all over Europe and the United States [7, 193].

Guidelines on cardiovascular diseases have considered total cardiovascular risk as the basis for treatment decisions for at least a decade. Simultaneously the treatment goal for hypertension has been under 140/90 mmHg, for total cholesterol under 5 mmol/l and LDL cholesterol under 3 mmol/l [234, 296] In updates of these guidelines and in newer guidelines the goals have tightened for high risk patients [54, 60, 105, 289–291]. Furthermore the preferred first line drug treatments for hypertension have changed over the past two decades [291–293]. It is evident, however, that treatment of cardiovascular risks is not in line with existing evidence and guidelines and changes in treatment practices are slow.

2.3 Guidelines

Guidelines are usually defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [141]. They are a synthesis of available evidence combined with expert assessment, formulated in recommendations – well-argued translations of scientific research [141, 264]. Each guideline covers prevention, diagnosis, treatment and rehabilitation or one viewpoint of a certain disease but seldom includes interprofessional division of tasks or recommendations for structures.

The amount of new knowledge is vast. Therefore clinicians need a synopsis of research findings to keep up-to-date. At the same time with the growth of evidence based medicine (EBM), the development of guidelines shifted from professional consensus to scientifically rigorous guidelines. According to EBM methods the validity of guidelines depends on the systematic work, especially systematically performed literature searches and evaluation of the existing literature [1]. Furthermore guidelines should be up-dated regularly to include new research findings.

Indeed, guidelines should be based on EBM methods to help health care professionals practice EBM. Evidence based medicine is about using best current evidence to treat patients [245]. When a physician practices EBM she uses both the best research findings and her expertise to make decisions about the patient's care. The hierarchy of evidence is often presented as a pyramid. At the top of the pyramid are such study types as meta-analysis, systematic reviews and randomised controlled trials and at the bottom observational studies. Nevertheless, users practising EBM are not restricted to the top of the study types; rather proper methods depend on the

question. Moreover purely EBM based decisions are rare because the experiences and values of the professional and patient as well as surrounding society influence decisions.

2.3.1 Aims of the guidelines

Guidelines provide practitioners as well as patients a tool for decision making [141]. The aim is to improve the quality of care and patient outcomes, and to decrease inappropriate variation. Despite thise fundamental aim, guidelines are used for various purposes, such as education, guiding resource allocations, and policy making [141]. Nevertheless, guidelines are not laws but rather should be applied individually taking into account the patients' personal characteristics [245, 264].

2.3.2 History of guidelines

The Dutch organisations have been pioneers and started the development of guidelines already in the 1980's [27]. On larger scale in the 1990's several countries established simultaneously guideline programmes. Some ten years later in a comparison of 18 guideline programmes Burgers et al. found that evidence based methods were widely adopted [27]. There were, however, some differences in the programmes. The development organisations were mainly professional societies or governmental agencies, and all except one received funding from the government. Patients were involved only in a few programmes, and pilot testing and guideline comparison was rare. Furthermore the implementation strategies varied. Along with the findings of the use of the evidence based methods there was a suspicion that the quality of guidelines was variable [108]. These observations led to at least three initiatives to improve guideline development.

Firstly, to facilitate high quality guideline development an international group of researchers, the Appraisal of Guidelines, REsearch and Evaluation (AGREE) Collaboration, developed and validated a generic instrument that can be used to appraise the quality of clinical guidelines [1]. The AGREE instrument was designed to evaluate the quality of the guideline development process and reporting of the process and it can not be used to assess the quality of evidence behind the recommendations nor the clinical content of the guideline. Secondly, although guidelines need to be developed nationally to accommodate the health care context, international collaboration in guideline development was seen beneficial. Therefore the Guideline International Network (G-I-N) was established in 2002 [220]. From its beginning it has grown to a network of 85 organisations and 79 individual members representing 43 countries (8). Thirdly, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group was established in 2000 to develop an approach to grade quality of evidence

and strength of recommendations [10, 119]. Finland has been among the pioneers in all these three initiatives.

2.3.3 Current Care Guidelines

National evidence based guidelines, Current Care (CC) Guidelines, have been developed since 1994 under the auspicious of the Finnish Medical Society Duodecim, the first published guideline being Celiac disease in 1997 [147](9). After ten years work, at the end of 2003 already 48 guidelines were published [147] and at the moment 101 guidelines are available (9). The guidelines cover a wide variety of clinical topics and a range of topics including: screening, prevention, diagnosis, treatment and management. The grading of the evidence is similar to GRADE including four levels (from A to D) (Table IV) and the evidence is visible to the reader through evidence summaries linked to each recommendation. The methodology follows the AGREE instrument to ensure high quality guidelines. A physician editor facilitates voluntary working group and a guideline developer's handbook is available for them (9). The aim is to start the updating of a guideline three years after its publication.

Table IV. Rules for grading the evidence in the Current Care Guidelines

Level A	Strong research-based evidence (multiple, relevant, high-quality studies with homogenous results, e.g. two or more randomised controlled trials, or a systematic review with clearly positive results)
Level B	Moderate evidence (e.g. one randomised controlled trial, or multiple adequate studies)
Level C	Limited research-based evidence (e.g. controlled prospective studies)
Level D	No evidence (e.g. retrospective studies, or the consensus reached in the absence of good quality evidence)

Reproduced with the permission of Finnish Medical Society Duodecim, Current Care guidelines.

From the beginning of the project, dissemination channels have included electronic publishing on CD-ROM and shortly afterwards the guidelines were available in an open access electronic format [146]. Other dissemination channels include publishing in a medical journal, re-prints and publicity. Implementation is supported by layperson versions and additionally is reinforced with slide series and web courses. Lately indicators have been developed together with the interactivity of the guidelines has been increased to support implementation. The strengths of CC guidelines are the wide target group of both primary and secondary care, open access format and offering layperson versions.

From single CC guidelines Hypertension and Resuscitation guidelines have been the most studied ones in the Evaluation of Current Care Effectiveness (ECCE) consortium [6, 206, 215]. These guidelines are well known and the implementation

efforts have led to some changes in division of tasks between doctors and nurses and improved clinical practices [6, 206, 215]. In addition a large programme studied the implementation of guidelines on major infections in primary care (MIKSTRA 1998–2002) [238]. Minor changes were detected towards the guideline recommendations [237, 238].

2.3.4 Attitudes towards guidelines

Possibly due to their open access dissemination through several channels CC Guidelines are widely known in primary care [5, 145, 170, 174], however the familiarity with individual guidelines seems to vary, [145] with the best known being the Hypertension guideline. Furthermore the guidelines covering drug treatment are more familiar than those concerning prevention by lifestyle changes [133, 170, 174]. In addition there is variation in the familiarity between the different health professionals; primary care physician being more familiar than those working in hospitals and nurses or physiotherapists [170, 174, 198]. Nonetheless the attitudes of all these professionals towards the guidelines have been positive [4, 170, 174, 242] and the CC guidelines are seen as important, reliable and clinically useful [145, 170, 174, 198] (10). In secondary care the attitudes have been positive as well although the guidelines in clinical pathways are underused [242].

Similar to Finland in Europe GPs are aware of the guidelines relevant to their practices [35, 36] but may not be familiar with specific content [183, 184]. Furthermore they mostly agree with the guidelines [82, 128], have positive attitude towards them [125, 181] and regard them as useful tools [128].

2.3.5 Criticism of guidelines

Although the guidelines are widely appreciated, several concerns and weaknesses have been recognised. In recent years there has been a lot of debate on the effects of the authors' conscious and unconscious biases, and conflicts of interest with the contents of guidelines [31, 233, 252]. Furthermore the failure to include all interested parties and such experts as epidemiologists, statisticians and economists, further diminishes guidelines' external validity [252]. In the Finnish context this culminates in the difficulties in finding GPs interested in guideline development.

The process of developing a guideline by a committee and consensus is slow and therefore a guideline and its evidence may be out-dated when it is first published [233]. Moreover concerns have risen about the different choice and interpretation of the evidence [189]. In some evaluations even half of the evidence has been derived from non-randomised trials or expert opinion [173, 265] while only from 11 to 16% of the evidence is from RCTs. In CC Guidelines the evidence has been of level A in 22% of recommendations in 2006 [156] and 25.5% in 2010 (unpublished data). The

level of evidence varied greatly between different topics such as pharmacotherapy and rehabilitation. In the Finnish context, the evaluation of evidence benefits from external review before publishing by improving transparency and thus increasing external validity [252]. Furthermore, in the Finnish context the great number of guidelines and viewpoint on diseases rather than on symptoms has been criticised [174, 213]. From a clinical point of view the guidelines focus on one disease and their applicability to those patients with comorbidities is not as good [182].

2.3.6 Use of guidelines

There is a high incidence of guidelines used in a self-report mode, and guidelines have effects on decision making [128, 145] (10). In addition organisations and regional health care providers should implement relevant guidelines locally by constructing house rules or common regional clinical pathways of primary and secondary care. Nevertheless, care pathways are quite rare [242] but there are some successful examples [149]. Furthermore the adherence of individual health professionals is not as high as reported [35, 36, 125]. Many studies have shown that there is an evidence gap, e.g. a difference between what is the best available research evidence and what is the actual clinical practice. In two studies from the Netherlands approximately two-thirds of recommendations were followed by GPs [115] and in the United States about half the care provided were evidence based [192]. The gap terms "clinical inertia" and "therapeutic inertia" are used especially for chronic diseases [217, 232]. Phillips et al. defined it as "failure of health care providers to initiate or intensify therapy when indicated" [232]. Furthermore O'Connors and colleagues categorised the underlying reasons for therapeutic inertia to doctor factors such as overestimation of care provided, patient factors and office (practice) system factors [217]. They estimated that the relative percentage of contribution to be 50% doctor factors, 30% patient factors and 20% practice factors. To minimize the gap different methods for adoption, e.g. implementation, of evidence are needed.

2.3.7 Implementation

Implementation means carrying out or executing a plan or a project. When considering clinical guidelines it represents three progressive ways with different efforts to introduce guidelines or evidence into practice [52, 264]. These three levels are diffusion, dissemination and implementation [52, 180]. Diffusion means the passive spreading of guidelines; for example via publication in medical journals or web. Dissemination includes targeted and tailored information and publicity for a specific audience whereas implementation is active efforts or interventions to adopt the guideline. The aim of implementation interventions is to overcome identified barriers and to change behaviour towards the guideline recommendations.

2.4 Managing change

Change and higher quality can be observed in health care at least in three different viewpoints; namely structures, processes and clinical outcomes [62]. It is fair to say, that change is difficult to achieve due to resistance to change. To overcome and understand these difficulties several theories exist on changing behaviour. Grol and colleagues have reflected on these theories in the health care context [116]. In the synthesis they have adopted Michie and Abraham's definition of a theory being: "a system of ideas or statements held as an explanation or account of a group of facts or phenomena". They further divide theories into process and impact theories.

Process theories explain how different implementation interventions should be planned and organised, and how the target group is affected by the interventions. Process theories include various steps to accomplish sustainable change. Earlier variations of these "step-of-change theories" are Roger's decision-innovation process, Prochaska and Velicer's trans-theoretical model and Pathman and colleagues' awareness to adherence model. Grol and colleagues made a synthesis of these step-of-change theories (Table V) where basic principles for accomplishing change are: a well-planned approach that takes into account the complexity of the practice, the commitment of target group, characteristics of the innovation, and other barriers for change. Furthermore consecutive and locally tailored approaches are needed, the change should be monitored, and implementation strategies must be incorporated into the structures for QI.[116]

The impact theories describe how an intervention leads through change. Grol and colleagues categorise these theories into those related to individual professionals (cognitive, educational, motivational theories), social context (communication, social learning, social network and influence, teamwork, professional development, leadership theories), organisational context (innovative organisations, continuous quality improvement, integrated care, complexity, organisational learning, organisational culture theories) and political and economic context (reimbursement, contracting theories).

Ideally a model for change should probably encompass both process and impact theories and act at each level of the impact theories; individual, group/team, organisation, and larger environment [73, 116] concerning barriers existing at all these levels. Theories focused on individuals consider 1) cognition: how decisions are made and what is the process of thinking, 2) education: the motivation to learn and different learning styles, and 3) motivation: attitudes towards preferred practice and the expected outcomes of the practice [116]. Between the single professional and the organisation teams can be seen as microsystems interacting in a macrosystem, i.e. an organisation or community [84]. These teams caring patients should have a common and clear goal since as Burnes has stated "to change anything requires the co-operation and consent of the groups and individuals who

make up an organisation" [29]. Indeed organisations are constantly seeking change to improve performance, they are learning along with individual learning and the knowledge is retained after individuals leave [116]. Besides someone or some group that intervenes in the running of the organisation, the change requires leadership [37] and organisational characteristics and complexity as well as organisational culture modify the organisations ability to adopt change [116]. Moreover building an effective team and redesigning multidisciplinary care processes are essential in changing organisational practices. Organisational learning has been described as a cycle of actions and reflection through continuous quality improvement [17]. One well-known example is the Plan-Do-Study-Act (PDSA) -cycle by Deming [56]. The change is led through four steps that require firstly establishing the aims of change, planning the change and evaluating the baseline performance, secondly implementing the change, thirdly reviewing and analysing the results and what has been learned, and fourthly acting based on what was learned. To help this reflection Elwyn and colleagues have developed a tool (Maturity Matrix) to assess the degree of organisational development and to plan improvements in primary care organisations [66]. This concrete tool, which illustrates the state of development, may further facilitate discussions about barriers.

Furthermore, especially in Canada the term knowledge translation (KT) is used. The Canadian Institute of Health Research defines KT as "a dynamic and iterative process that includes synthesis, dissemination, exchange, and ethically-sound application of knowledge to improve the health outcomes, provide more effective health services and products and strengthen the health care system" (11). This term integrates knowledge creation and application [106]. The theory focuses on health outcomes and changing behaviour, therefore it is placed in the practice setting (social, organisational and policy environment rather than in learning situations) [51]. It identifies best evidence and uses different tools and interventions to overcome barriers to change from awareness through agreement and adoption to adherence. While continuing medical education focuses on individuals and groups, KT allows the multidisciplinary participation of all in healthcare practices; it is learner driven to a lesser extent.

Table V. A model for planning change

Stage	Possible barriers	Possible strategies and interventions
Orientation (awareness and interest)	Not familiar, does not read the literature, does not see relevance	Distribute messages via different channels, approach key persons and target group, performance information
Insight (understanding, insight into own routines)	Lack of knowledge, complex and too extensive information, unrealistic insight of one's own practice	Well-planned, concise, and repeated information, information on problems, audit and feedback, benchmarking
Acceptance (positive attitude, decision to change)	Sees disadvantages, doubt about values, not attracted to change, doubt about feasibility, success, and one's own efficacy	Local adaptation of the innovation (discussions and consensus), discuss resistance, present evidence, use opinion leaders and peers, seek solutions and barriers, suggest realistic goals for change
Change (adoption/try out, confirmation of value)	Lack of time and skills, incompatible with routines, insufficient success, negative reactions of others	Extra resources, training, and support, development of processes, information material for patients, plan goals for change, evaluate problems, find solutions
Maintenance (new practice integrated into practice, embedded in organisation)	Relapse, forgetting, no organisational support or resources	Audit and feedback for individual and organisational level, reminder system, local care plans and protocols, provide resources and support from management, rewards

Modified from Grol et al. 2007 [116].

2.4.1 Barriers for changing behaviour and implementing guidelines

The knowledge on barriers and facilitators for changing clinical practices is mainly derived from observational studies and theoretical consensus statements. Several systematic and unsystematic reviews have been published, one being a meta-review [85]. The categorisation of the barriers has varied but at least four major categories can be identified: factors related to individual professional, innovation itself e.g. guideline, patient, and the environment [30, 85, 112] where the environment includes both organisation and society. In a somewhat different classification to that above, Fleuren et al. grouped facilitating or hindering determinants of adoption of health care innovations into four categories [79] (Figure 2). They perceived organisational determinants as one major category, and patients' characteristics were seen as characteristics of the socio-political context (environment). Moreover they recognised that the characteristics of the implementation strategy are an important piece of the puzzle.

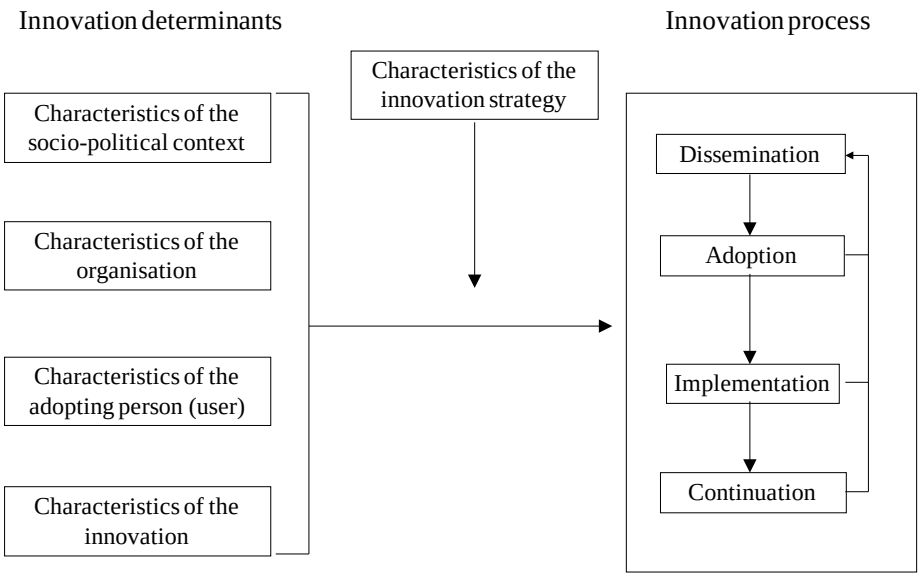

Figure 2. Framework representing the innovation and related categories of determinants Fleuren M et al. Determinants of innovation within health care organizations. Literature review and Delphi study. Int J Qual Health Care 2004;16(2):107–23 [79] by permission of Oxford University.

In a systematic review Cabbana et al. categorised the professional barriers for adopting evidence as knowledge (lack of awareness and lack of familiarity) and attitudes (lack of agreement, self-efficacy, outcome expectancy, or the inertia of previous practice) [30]. In addition the need for new skills hinders the adoption [28, 36, 115, 196].

The most frequent barrier associated with guidelines themselves has been complexity [85]. Michie et al. defines it as wording [197]. Vague, non-specific and unclear recommendations are hard to follow; instead a precise recommendation would include active verbs and describe what, who, when, where, and how [197]. On the other hand there are some details that facilitate a guideline's use. Such details include the recommendations being in line with the existing values and norms and supported by sound evidence [28, 85, 115, 181, 184]. Moreover the importance of the guideline topic and the advantage of the new care processes act as a facilitators [253]. Adherence is also improved with increasing sense of ownership when the target group has been involved in the development of the guideline [36, 85, 116]. And actually, the aforementioned professional barrier, an individual's disagreement with the recommendation, can reflect characteristics of the guideline itself, for example a lack of evidence or a lack of applicability. General practitioners argue that population-based trials are not necessarily applicable to individual patients and that the guidelines should be more flexible [36] especially in terms of individual characteristics of a patient such as co-morbidities and age [30, 36, 85].

Besides professionals, patients can have negative attitudes toward evidence-based treatments [36, 85, 128, 184]. As a consequence physicians suspect that they might jeopardise the doctor-patient relationship if they too strongly recommend treatment options.

The environmental context includes barriers related to systems or organisations and to the social context. Solberg et al. found the barriers related to organisation to be the most important ones [253]. The presence of organised systems and a change management infrastructure are important in addition to committed leadership [79]. The social context further includes support from peers [85, 196, 253] and relationship between primary and secondary care [86]. Furthermore, a frequently mentioned environmental barrier is the lack of different resources (e.g. time, personnel, costs, availability of innovations) [30, 36, 85, 202]. The GPs and their teams, the microsystems, act in larger environments that regulate practices through economic and political decisions. These decisions such as reimbursement systems do not always support evidence-based practices [196].

Special consideration should be taken to prescribing decisions. Although the same aspects – personal experiences and knowledge, expectancies about treatment outcomes and values of these outcomes (efficacy, side effects, costs), and social environment – have impact on drug choices; it has been argued that nearly 40% of prescribing is habitual [57]. The values in decision making somewhat differ for different disorders but irrespectively disease efficacy has been observed to be the most important value [58]. Furthermore professional attitudes are important while patient preferences do not have a consistent effect on drug choices. In addition to other environmental aspects, the marketing activities of the drug industry have an impact on prescribing [107, 255] especially in the adoption of new drugs [107].

As a synthesis it can be said that whatever the framework might be, it seems that barriers vary between innovations such as guidelines and between recommendations [181, 183]. When planning an implementation intervention the possible barriers should be considered and the interventions tailored to overcome any identified barriers.

2.4.2 Effects of different implementation strategies

Different implementation interventions can be categorised as health professional or organisation oriented, patient mediated, and financial interventions [264]. It has been suggested that at least both individual and organisational interventions are needed to accomplish change [114]. Furthermore it has been suggested that multifaceted interventions are more effective than single ones [15, 110] but a high-quality systematic review found no evidence for this [109]. However, tailoring for specific settings and target groups is needed [109, 113]. In the following the different interventions are categorised according to Thorsen and Mäkelä [264].

Interventions oriented towards health professionals include distribution of educational material, didactic and interactive education, local consensus procedures, outreach visits, local opinion leaders, audit and feedback, and reminders.

Simple distribution of educational material has modest or no effect on clinical practices [53, 109]. Continuing medical education (CME) refers to education after certification and licensure and is often group-based. According to a meta-analysis including 61 studies, the effect of CME on physicians' knowledge is moderate but small for performance and patient outcomes [187]. A more recent Cochrane review concluded similarly for performance and patient outcomes, the median effect size being 6% [83]. Furthermore mixed educational interventions seem to be more effective than single ones [83, 187] and the effect is larger for active interventions such as interactive workshops and individual training than for passive ones [187, 235]. On the other hand the Cochrane review did not confirm this observation [83]. According to the authors one possible explanation is the difficulty of categorising these interventions.

Opinion leaders are people who are seen as pleasant, trustworthy and influential [81]. Although their role and tasks are seldom described in reports, interventions with opinion leaders appear to induce change [81], even though, the effect has been of variable size [81, 235]. In these reviews the authors have not separately reported the effects on clinical practices and patient outcomes.

Educational outreach visits (EOV) or academic detailing can be defined as "a personal visit by a trained person to health care professionals at their own settings" [218]. The detailing is often arranged as one-to-one meetings in contrast to a group sessions. The meetings are based on information on how to change performance and overcome barriers to change practices. Personal feedback is often used to illustrate the need for change. Outreach visits have often been used to change prescribing practices. Both educated pharmacists and physician counsellors have been used as well as nurses. Already in a review including data from 1970 to 1988 there was evidence that face-to-face educational outreach visits can be effective in reducing inappropriate prescribing [254]. A more recent Cochrane review included 69 RCTs with different health care professionals and target practices half of the interventions being multifaceted [218]. For the studies health professional outcomes improvement in compliance with target behaviour was moderate being especially coherent for 17 studies aiming to reduce inappropriate prescribing. The results for other types of professional behaviour were more variable. When comparing individual and groups sessions (three studies) there were controversial results and when comparing audit and feedback to the outreach visits, visits seemed to be slightly more effective. Furthermore the results suggest that when using EOV as a part of a multifaceted intervention it is more effective [218]. In the primary care setting the findings of the Cochrane review are supported by more recent studies where outreach visits

were a part of a multifaceted intervention [16, 200, 297]. Controversial evidence exists but in two [22, 210] out of three [22, 210, 301] of these studies the outcome measures have been patient-related.

Reminders can refer to different interventions including manual and computerised interventions. Computerised decision support is discussed in more detail in the section handling organisational interventions. In numerous studies reminders have proven to be consistently effective [15, 109], and more effective than classical feedback [110]. In the later systematic review the median effect size was +14% [109].

Feedback can be defined as the use of comparative information from a statistical system or a summary of clinical performance given in a written, electronic or verbal format [143]. In an audit the actual performance is compared to planned performance or an external standard. The strategy of combined audit and feedback has had variable effect on practice performance [110, 143, 235]. On the other hand Grimshaw et al. observed modest consistent improvement in performance: median effect size in absolute improvement was 7% [109]. Furthermore, the lower the baseline adherence the greater was the observed improvement in performance [143]. In the Cochrane review there were three publications, parts of one study, which reported patient outcome measures [143]. None of them showed differences between the groups.

On **financial interventions**, incentives, a fairly recent Cochrane review offers an overview of previous reviews up to January 2010 [80]. In the review an incentive is defined as "any factor (financial or non-financial) that provides motivation for a particular course of action, or counts as a reason for preferring one choice compared to alternatives" and financial incentives as "extrinsic sources of motivation which exist when an individual receives a monetary transfer which is made conditional on acting in a particular way". The authors grouped the financial incentives into five groups: payment for working for a specified time period, payment for service, payment per capita, payment for quality of care, and mixed or other systems. In conclusion in all types of incentives over two-thirds of the studies showed improved outcomes except payment for working for a specified time period. Furthermore mixed systems had mixed effects. When looking at outcomes the incentives were generally effective in improving the process of care although ineffective in improving compliance with guidelines. [80]

The most familiar incentive system in primary care is probably The United Kingdom's National Health Service's Quality and Outcome Framework (QOF) where additional government payments to family practitioners are based on the quality of delivered care. This voluntary scheme was introduced in 2004 [243] (12). The indicators measure organisation of the practice, patients' experiences, and additional services (preventive services such as child health surveillance) (12). The performance results of the included practices are published annually. According to results of the

QOF it seems that pay-for-performance can be an effective way of changing clinical practices and clinical outcomes for included patients [33, 64, 65] at least for some conditions [34]. In an interrupted time series at two time points before (1998 and 2003) and after (2005 and 2007) the implementation of the QOF scheme induced improvements in quality for asthma and diabetes but not for heart diseases which had been improving already before the introduction of the QOF [34]. Furthermore it seems that once targets are reached, the improvements get slower; the plateau phase starts already after one year [34, 63]. Nevertheless the practices perform better for those indicators linked to incentives than for those not linked to incentives where the change may even be reversed [34, 63]. In modelling studies the health gains of the system have been evaluated to be apparent and cost-effective [77]. The benefit in some cases may, however, be limited due to low target performance of indicators for full payment incentive and the threshold for cost-effectiveness varies greatly. It is also noteworthy that the evaluations concern a limited number of conditions and indicators, and use short-term data up to three years.

Organisational interventions include staff-oriented interventions (change in task dividing, teamwork, and case management) and structural changes (information technology (IT) systems, patient tracking system).

A review of organisational interventions included 36 reviews with variable interventions and outcomes [283]. The authors, however, concluded that a revision of professional roles might improve performance while positive outcomes for patients were uncertain. On the other hand multidisciplinary teams may improve them. Organisational interventions and changes are often related to care of chronic illnesses especially in terms of enhanced teamwork and better division of tasks. At least one model in primary care, the Chronic Care Model, exploits this approach as one core change needed [21]. In addition the model emphasizes effective use of community resources, strong leadership and goal setting, self-management, and computerised information system along with decision support. The Chronic Care Model or its components have often been implemented by collaborative strategies. At least some of the monitored process and outcome measures have showed moderate improvements in controlled before and after study designs [42, 248].

The collaborative –method is a short-term learning system that brings together a large number of teams to work for the improvement of a focused topic [248]. As a part of a collaborative, teams attend a series of meetings where they learn about best practices in their target area, quality improvement techniques, and the experiences of others. The core idea is to set aims, collect data and test change. The results of collaborative have been mixed and the methodological quality of the studies poor with uncontrolled design or even with only post measurements [248]. Other QI initiatives, such as PDSA–cycles, could also be included in organisational interventions. However, this kind of research has often been initiatives of

organisations rather than studies of research teams [111] and possibly has not been reported in scientific journals.

New task divisions have been forced on primary care due to constrain on resources all over the world. In some countries the duties of nurses, so called practice nurses, has been enhanced [249]. The new tasks have included limited prescribing rights or prevention of chronic illnesses, also called case management. Case management and nurse led secondary prevention clinics have had small positive effects on patient outcomes [32, 40, 59, 227, 288] although the results have not continued to improve in longer follow-ups [32, 204, 205]. Contrary evidence exists but the differences in interventions [162], patients and settings [168] may explain the differences. There is little evidence for differences between the way GPs and nurses prescribe, but it seems that nurses are more likely to adhere to the guidelines [267]. To summarise, a Cochrane review concludes that trained nurses can produce as high a quality of care as GPs and achieve as good health outcomes for patients [172]. However, due to short follow-up, methodological limitations, and the fact that only one study had power to assess equivalence of care, these findings should be treated with caution.

Clinical decision support systems (CDSS) provide clinicians with patient-specific assessments or recommendations to aid clinical decision-making. Along with the development of electronic patient records electronic CDSSs with different features have become more common. Kawamoto and his colleagues reviewed 88 publications of 70 studies to identify system features of CDSS critical to improvement in clinical practices [152]. Independent predictors were integrated automatic system, provision of recommendations, provision of decision and support at the time and the location of decision making, and computer based systems. But low adherence to the system may be a problem [247] as well as an excessive number of reminders [271]. Several reviews on improvement potential of CDSS have been published and at least one solely on interventions in primary care setting [26]. The improvement effects have been variable; the percentage of successful interventions in practice performance has been from 57 to 85% [26, 98, 144, 246] but they were lower for patient outcomes (13%–30%) [98, 144]. Bryan et al. reported that studies with neutral or variable results had more methodological limitations [26]. In more recent studies on primary care setting, the effect has been small to moderate [101, 219]. As in other QI the effect has been larger with lower baseline adherence [282].

An electronic CDSS, Evidence-Based Medicine electronic Decision Support (EBMeDS), has been developed and used also in Finland (13). The system receives structured patient data from electronic patient records and returns reminders, therapeutic suggestions and links to guidelines. It can also be used to bring patient data to electronic forms and calculators. In addition to QI, the EBMeDS decision support rules can be run in patient populations (known as virtual health checks).

Multifaceted interventions can include different mixes of components for interventions described above. It has been argued that multifaceted guideline

implementation is more likely to be effective than single interventions because it approaches several barriers of change at the same time [110, 235]. But in a more recent systematic review single interventions seemed to be as effective as multifaceted ones [109]. A meta-review, however, concluded that there is more evidence on multifaceted interventions than on single ones [235]. Nevertheless there is no relationship between the number of implementation strategies and the effectiveness of the intervention [109, 235].

To find primary studies on multifaceted guideline implementation in primary care a PubMed search was conducted (8.8.2011). The terms used were "primary health care" [MesH] OR "family medicine" [MesH] AND "guideline adherence" [MesH] AND "multifac*". The search yielded 26 abstracts from 2001 to 2010. After reviewing the titles and abstracts seven were excluded from the summary in Table VI; two were reviews, two had no intervention, and three are described in detail in the facilitation section of this thesis [92, 94, 269]. One study had several publications [90], leaving 15 separate studies. Two of the studies acted as controls for each other's but the intervention results were reported separately [16, 22]. Further three studies of the same researchers followed a very similar study design with four different conditions [297–299]. Duplicate publications were searched for if they were mentioned in any of the texts and one was found describing the study methods [228].

Eight of the studies were RCTs [13, 14, 16, 22, 88, 227, 284, 297] and most often the unit of randomisation was practice. Follow-up time varied from 3 to 48 months. Interventions and outcome measures differed across the studies. All the studies, however, included components targeted towards health professionals. Six included components towards organisational changes [16, 22, 90, 127, 191, 284], and two included patient mediated interventions [191, 227]. Only one national implementation programme used financial interventions (reimbursements) [127]. The target behaviour was most often preventive actions either concerning CVDs or cancer.

Multifaceted interventions are rarely replicated as such and therefore summarising the results is difficult. Process measures were often used [14, 16, 22, 88, 127, 171, 191, 227, 250, 277, 284, 297–299]. In addition six reported results on patient mediated or clinical outcome measures [13, 22, 88, 191, 227, 284], while only one reported structural outcomes [127]. In two studies the primary outcome was related to GPs self-efficacy and need for education [171, 284].

The improvements were small to modest and patient outcomes were rarely improved compared to the process measures. Overall three studies did not report statistically significant improvements in any of the outcomes [22, 277, 284] and one did not state the significance of the improvements [191]. There are several possible explanations for the failure. Firstly, Bonds et al. targeted the intervention towards professionals while they measured mainly patient outcomes [22]. Secondly, the

attendance to the education sessions by target group members was low [277, 284] and the group was unaware of the intervention IT-system [284]. Therefore a lack of actual intervention could have led to observed ineffectiveness. Thirdly, two studies involved a patient group that is rarely met in primary care [277, 284].
The cost-effectiveness of guideline implementation strategies are infrequently reported, and they do not include all relevant costs from guideline development to its implementation [109, 235]. In one study the estimated costs per quality-adjusted life year gained by patients with atrial fibrillation or transient ischemic attacks were both less than £2000; very much less than the usual criterion for cost effectiveness [297]. On the other hand, in an other study there were no savings from a significant shift in prescribing antihypertensive drugs towards the use of thiazides; the cost of the intervention were more than twice the savings during the follow-up but modest savings were predicted over a two-year period [87]. However, there is evidence that treatment according to guidelines can save costs and be cost-effective at least for some patient populations [23, 163] .

In summary most interventions are effective in specific contexts and none are effective in all situations in changing clinical practices and guideline implementation. Therefore knowledge on the setting involved is needed and thereafter there should be tailoring of interventions. The effects of various strategies have been small to modest.

2.5 Facilitation

The word facilitation is of Latin origin. It comes from the word “facil” which means the same as the English word “easy”. Facilitation in organisations and in business is common and it involves planning and conducting successful group processes and meetings. A facilitator is a person who leads the process. Usually the facilitator is content neutral and goal oriented, and has no substantive decision–making power. The facilitator uses different techniques and tools to enhance the work of the group and its individuals. Facilitation is ideally used to utilise the different expertise of individuals in an organisation in situations where combining numerous expert opinions and knowhow is needed. The aim is, with the help of the facilitator, to identify and solve problems, make decisions and reach consensus. To reach consensus after free innovation, the group discusses and decides which solutions and actions are needed. [46, 214] (14,15)

In health care context the facilitator concept has been widely used in England from the early 1980’s and thereafter implemented in Australia, Canada, the Netherlands and the United States [209]. Different versions of facilitator title have been applied, for example educational facilitator, nurse facilitator and practice enhancement assistant. The role of a facilitator has been similar as in the business

Table VI. Multifaceted guideline implementation interventions in primary care and statistical significance of improvements

				Intervention				Significant improvement		
Reference	**Country, study type, follow-up time (mo)**	**N of practices, intervention/ control**	**Target behaviour**	**Professional**	**Organisational**	**Financial**	**Patient-mediated**	**Structure**	**Process**	**Outcomes**
Peters-Klimm et al. 2010 [227]	Germany RCT, 12	99/100*	Management of CHF	A&F, GL, R	CM		EM, diary		No	**No** Yes/No
McCraw et al. 2010 [191]	USA BA, 12	2	Management of T2DM	CME, OL, R	CM, NR , PTS, TD, TW		EM, F		**NS**	**NS**
Bertoni et al. 2009 [16]	USA RCT, 36	29 / 32	Management of cholesterol	A&F, CME, EOV, GL	ITS				**Yes** Yes/No	
Bonds et al. 2009 [22]	USA RCT, 24	32 / 29	Management of BP	A&F, CME, EM, EOV, GL	NR				No	**No** No
Becker et al. 2008 [13]	Germany RCT, 12	37 / 38 / 43	Management of low back pain	CME, EOV, GL CME, EOV, GL	CM, TD, PTS					**No** Yes/No
Wright et al. 2006 [298]	UK CBA, 48	43 / 37	Management of TIA	A&F, CME, EM, EOV, GL, M, OL, R					Yes/No	
Wright et al. 2007 [297]	UK RCT, 21	33 / 44	Implementation of AF and TIA guidelines	A&F, CME, EM, EOV, GL, M, OL, R					Yes/No	
Wilson et al. 2006 [284]	Scotland RCT, 6	57 / 29	Breast cancer	CME	ITS				No	
Fretheim et al. 2006 [88][14, 88]	Norway RCT, 12	70 / 69	Prescribing	A&F, EOV, GL, R	ITS				**Yes/No** Yes	**No** No
Bekkering et al. 2005 [14]	Netherlands RCT, 19	52 / 61**	Management of low back pain	A&F, CME, GL, R					Yes	
Waldorff et al. 2003 [277]	Denmark CBA, 12	425 / 128	Dementia	CME, EOV, GL, R					No	
Wright et al. 2003 [299]	UK CBA, 10	99 / 81	Asthma and stable angina pectoris	CME, EOV, GL, OL, R					**No**	**Yes/No**

Silagy et al. 2002 [250]	Australia CBA, 3	200 / 200**	Implementation of guidelines: stroke and lower urinary tract symptoms in men	CME, GL, M, R					Yes/No	
Hermens et al. 2001 [127]	Netherlands National cohort, 30	988	Cervical cancer screening	CME, EM, EOV	ITS, TD	Reim-bursement		Yes	Yes	
Lane et al. 2001 [171]	USA CBA, 36	128 / 154**	Breast cancer screening	CME, EM					No	

RCT= randomised controlled trial; BA= before and after design, no controls; CBA= controlled before and after design; CHF= chronic heart failure; T2DM= type 2 diabetes; BP= blood pressure, TIA= transient ischemic attack; AF= atrial fibrillation. * number of patients; ** number of health care professionals

Professional interventions: audit and feedback (A&F), education (CME), distribution of educational material (EM), educational outreach visits (EOV), distribution of guidelines (GL), marketing (M), opinion leaders (OL), and reminders (R). Organisational interventions: case management (CM), information technology systems (ITS), local guideline development (LGL), new resources (NR), patient tracking systems (PTS), task dividing (TD), and teamwork (TW). Patient mediated interventions: educational material (EM), feedback on treatment balance (F) Improvement: primary outcomes bolded, NS= significance Not Stated.

world; facilitators act as catalysts of change, change agents, and support the use of different tools; but they have not been purely neutral to the content [38, 96, 209, 257]. The lack of neutrality is presumably due to research and project situations; the facilitators facilitate the change toward the projects aims. However, the task is to work with the practice staff to discover where they are now, where they would like to be, and how they can get there [240, 257]. To achieve this progress in facilitated sessions, facilitators need different skills, such as listening, questioning, encouraging, challenging, reflection, and summarising. The sessions are construct from four areas: structuring the session, obtaining consensus, handling group dynamics, and enabling team learning. The most difficult area seems to be, even for experienced facilitators, to lead the team from discussion to deciding on the needed improvements and actions [240].

Facilitation is close to academic detailing (educational outreach visits) used as well in health care and sometimes these studies are difficult to differentiate between. In conclusion, academic detailing is individual, not group-based or organisation oriented, and has more limited number and length of contacts. Moreover facilitation is more two-way communication [257]. In the following literature studies have been included if the authors have stated that they used facilitation or facilitators even though they might as well use the term outreach visits. The study by Cockburn et al. [41] is closest to academic detailing with just two brief visits to individual GPs.

2.5.1 Facilitators

Fullard and colleagues conducted one of the first studies on facilitation in the 1980's with a nurse facilitator [95, 96]. Thereafter facilitators have been mainly nurses or practice assistants, from outside the practice and mutual for several practices (Table VII). Some exceptions exist: in one study some of the facilitators (23%) were current practice staff members [190] and in two a physician [49, 229]. As described earlier, facilitators need skills that are not necessarily learned in vocational training and therefore specific facilitator training is needed. This training of the facilitators has, however, been rarely described in detail (Table VII). Some extensive training programmes have been used; Lobo and colleagues [93, 94, 178] have used 80 hours of training with lectures and visits to pilot practices and Lemelin et al. a 30-week programme [12, 132, 175].

2.5.2 Studies on facilitation

According to a review many prospective, uncontrolled studies and a few randomized, controlled trials have documented the effectiveness of facilitation [209]. After the review, several new studies have been published (Table VIII). Of the 13 studies not included in the review, seven [93, 129, 178, 190, 200, 216, 269] were RCTs. The

unit of facilitation has usually been a practice with some exceptions [41, 229]. The three main areas of target behaviour; prevention, management of chronic diseases, system-level improvements recognised by Nagygaldi et al. [209] seem still to be current (Table VIII). The intervention has always been multifaceted and often tailored according to the needs of a practice. Education and audit with feedback have been often combined with facilitation. The intensity e.g. number and length of the visits have varied from a couple of times [39, 41, 61] and short 5 to 10 minutes visits [41] to over twenty times [135, 175, 200] and visits lasting even a couple of days [216, 258] (Table VII). It is, however, often impossible to say what the facilitation includes in its entity. Besides the facilitated sessions, preparing and planning the sessions is needed and administrative duties as well as travelling take time. Indeed, the time used facilitating can be under 20% of the facilitators' total time [12]. Furthermore the length of the intervention and follow-up has varied from 3 months [41] to over two years [124, 216].

Due to variations in target behaviour, interventions and outcome measures it is difficult to reach conclusions on the results of facilitated interventions (Table VIII). Structural changes have been measured in six studies [49, 136, 178, 190, 200, 216] with mainly positive results even though the implementation of structural changes has varied between practices. Similarly the results in process measures have varied. A few studies have measured patient outcomes [190, 216, 269] with mainly negative results [190, 269].

It has been argued that the facilitator approach is costly [41, 92]. The costs in these varying interventions have been from a couple of hundred US dollars or euros [41, 94] to approximately 4500 euros or more [176, 178, 200]. However, estimated cost savings of an extensive intervention overrun costs of the intervention and induced changes [131].

2.5.3 Determinants of successful facilitation

Three different aspects can be discerned when analysing the success of the facilitation interventions: 1) facilitator, 2) intervention, and 3) organisation (Table IX).

In a project evaluation including nearly 200 facilitators Petrova et al. recognised three different types of facilitators: "driver of practice change" (proactive ones), "partner in practice change" (proactive actions signs of limited interest and primarily the responsibility for the advance of practices), and "available if requested" (the minimal amount of time spend in their facilitator role) [230]. Nevertheless the authors found no evidence that differences in facilitators' personal characteristics had any effect on their abilities to stimulate practice change. On the other hand an association between facilitators' professional background and the extent of practice change was found; practices facilitated by a GP achieved higher levels of change than practices facilitated by a clinical nurse specialist. This finding has been

Table VII. Description of facilitators and intensity of facilitation.

Reference	Facilitator	Training	Mean n practices / facilitator (range)	Mean n visits (range)	Mean length of visits (h)	Total time used
Aspy et al. 2008 [9]	Not stated		3			
Chan et al. 2010 [39, 122]	Nurse or other			3		
Cockburn et al 1992 [41]	Nurse or respiratory physiologist	Extensive		2	0.2	
Dale et al. 2009 [49, 203, 230]	General practitioner, nurse or else	Nationally coordinated	7.5 (1–78)	3.3 (0–20)		10 h/week (range 0–37.7)
Dietrich et al. 1992 [61]	Not stated	Extensive	8.3	3		
Frijling et al. 2002 [94, 176]	Practice assistant or other	Lectures (80 h; facilitation, project protocol and clinical issues) and pilot facilitation visit		15	1	
Frijling et al. 2003 [93, 176]	Practice assistant	lectures (80 hours; facilitation, project protocol and clinical issues) and pilot facilitation visit	Up to 20	15.2 (4–17)	0.95	43 h (preparation, visits, reporting, waiting)
Frijling et al. 2003 [92]	Practice assistant or other	10 half-day workshops, regional meeting 5 times a year, newsletter bi-monthly		4		
Fullard et al. 1987 [95]	Nurse		3			
Geboers et al. 1999 [99]	Practice assistant	Facilitation, model, quality techniques and tools	10	6		
Goodwin et al. 2001 [104]	Nurse	Qualitative research methods, pilot of practice assessment	19	6 (2–9)		
Hearnshaw et al. 1998 [124]	Not stated		13.5	9	2	

Hogg et al. 2008 [129]	Nurse	4-week theoretical training (medical practice management, prevention and social learning theory, ITS, EBM, audit, facilitation) and 3-week practical component (pilot intervention and audit)	13.5	9	0.8	
Hogg et al. 2008 [130]	Nurse		9			
Hulscher et al. 1997 [136]	Nurse	Carefully trained, pilot intervention	5.5	25	1.2	30 h
Lemelin et al. 2001 [12, 132, 175]	Nurse	30 week intensive training (course work, assignments, practical experience, planning)	7.3	33 (21–50)	1.75	Mean 2642 h
McBride et al. 2000 [190]	Nurse, dietitian or health educator	2-day workshop (protocol, facilitation, clinical issues)	1			4.5h/week
Mold et al. 2008 [200]	Nurse		2.6	17.8 (8–42)		7.4 h (1.3–44)
Nutting et al. 2010 [216]	Diverse backgrounds outside health care	Three months of training (practice change, the model components, facilitation) and continued training throughout the project with ongoing discussions and visits or conference calls with experts and outside consultants		(5–8)	1 to 4 days	
Petrella et al 2007 [229]	Family physician	Training in the programme goals			1.25	
Van Bruggen 2008 [269]	Nurse			2 visits/ month	3	

Table VIII. Description of studies including facilitation and improvements in outcomes

				Intervention				Improvements			
Reference	**Country, study type, follow-up time (mo)**	**N of practices, intervention/ control**	**Target behaviour**	**Professional**	**Organisational**	**Financial**	**Patient-mediated**	**Structure**	**Process**	**Outcomes**	**Other**
Aspy et al. 2008 [9]	US BA, 6–12	10 *	Screening and counselling	A&F, CME	Q	+			Yes/No		Adoption Maintenance
Chan et al. 2010 [39]	Australia BA, 6	26	Teamwork	A&F, CME, EM, WT		+					Improvements in collaboration
Dale et al. 2009 [49]	UK BA, 6–12	1305	Palliative care	CME, WT	CoM	+/-		Yes	Yes		Self-assessment of palliative care
Frijling et al. 2003 [93]	Netherlands RCT, 21	61 / 60	CVD guidelines	A&F, CME, EM					Yes/No		
Hogg et al. 2008 [129]	Canada RCT, 13	27 / 27	Prevention guidelines	A&F, CME, EM, WT	CoM				No		
Hogg et al 2008 [130]	Canada BA, 15–21	27	Prevention	A&F, EM, OL, R	CoM				Yes/No		
Hulscher et al. 1997 [136]	Netherlands CBA, 18	33 / 31 / 31	Organisation of prevention	A&F, CME, WT	CoM, TD, PTS			Yes/No	Yes/No		
Lobo et al. 2002 [178]	Netherlands RCT, 21	62/62	Organisation of CVD prevention	A&F, CME, EM				Yes/No	Yes/No		
McBride et al. 2000 [190]	USA RCT, 12	11 / 11/ 11 / 12	Practice systems for CVD prevention	A&F, CME, EM, Q	CoM			Yes/No	Yes/No	Yes	Goal setting
Mold et al. 2008 [200]	USA RCT, 6	12 / 12	Preventive services	A&F, EOV, R	CoM, IT support			Yes/No	Yes/No		
Nutting et al. 2010 [216]	USA RCT, 26	16 / 15	Practice model	A&F, CME	CoM, ITS, Q			Yes		No	

Petrella et al 2007 [229]	Canada BA, 2–3	659*	Musculoskeletal disorders	CME, OL							Knowledge, satisfaction
Van Bruggen 2008 [269]	Netherlands RCT, 12	822 / 818 **	Diabetes guideline	A&F, CME, EM, GL	LGL, TW				Yes/No	Yes/No	

RCT= randomised controlled trial; BA= before and after design, no controls; CBA= controlled before and after design; CHF= chronic heart failure; T2DM= type 2 diabetes; BP= blood pressure, TIA= transient ischemic attack; AF= atrial fibrillation. * number of health care professionals; ** number of patients from randomised practices .

Professional interventions: audit and feedback (A&F), any education (CME), distribution of educational material (EM), educational outreach visits (EOV), distribution of guidelines (GL), marketing (M), opinion leaders (OL), and reminders (R), working tools (WT). Organisational interventions: case management (CM), consensus meetings (CoM), information technology systems (ITS), local guideline development (LGL), new resources (NR), patient tracking systems (PTS), quality improvement (Q), task dividing (TD), and teamwork (TW). Patient mediated interventions: educational material (EM), feedback on treatment balance (F).

supported [176, 179] but contradictory findings exist as well [281]. Furthermore group facilitation skills, good relationship with the facilitator, and continuity of the facilitator have been found to be related to the achieved change [132, 257, 281].

As facilitated intervention is typically multifaceted the other components have an effect on its success or failure. Audit and feedback seems to have used in almost all facilitated interventions. In an effective tailored intervention, the most used approaches were audit and feedback, consensus building, and implementation of a reminder system [12]. Therefore the authors recommend using these three intervention elements with facilitation. In another study the same authors suggest that the ineffectiveness of a similar intervention is due to too many target behaviours and too many practices per facilitator [130]. One further determinant of success has been duration of exposure to programme aspects and number of visits or hours spent on facilitation [179].

The organisational characteristics seem to strongly affect the change potential of a practice. Typical characteristics for a "developing practice" are committed leadership, experience in quality work, support by a feasible electronic patients system, use of feedback, effective communication, and investment in time [67, 68, 92–94, 129, 132, 203]. The interaction should be interprofessional [67, 129, 132, 203]. Financial compensation may moreover improve commitment to the programme [92]. Opposite to successful practices those who fail often have weak leadership, lack of respect from manager for facilitation, poor communication and an inability to make decisions, and therefore narrow ownership of initiatives [67]. Other hinderers of change are low staff involvement, lack of a computer system, high staff turnover, and conflicting organisational priorities [9, 132, 203].

Table IX. Determinants that may induce successful facilitation

Facilitator	Intervention	Organisation
• Continuity • Flexibility • Group facilitation skills • Organising skills • Personal characteristics • Professional background • Relationship with the group	• Components (for example audit and feedback, consensus methods, reminders) • Few practices per facilitator • Financial incentives • Intensity and length • Limited number of target behaviour • Open measures	• Experience in quality work • Electronic systems • Good team relationship and communication • Leadership and management • Low stuff turnover • No other major projects • Staff involvement and positive attitude • Time invested • Use of feedback

3. AIMS OF THE STUDY

The general aims of the present study were to assess the effects of a multifaceted facilitation intervention on structures, organisational practices and individual practices in CVD prevention and treatment in one organisation, and to study the long-term effects of a lifestyle intervention on CV risk factors.

The specific aims of the study were

1. To describe the intervention and to assess the effects on structures and treatment processes at the organisational level.
2. To approximate the effects of the intervention on workload due to BP measuring and lifestyle counselling.
3. To study the effects of the intervention on antihypertensive prescribing.
4. To study the long-term effects of a lifestyle intervention on cardiovascular risk factors.

4. MATERIALS AND METHODS

This thesis is based on four original studies. The design of the studies is briefly described in Table X.

Table X. Brief description of individual studies presented in this thesis.

Study	Design	Data	Outcomes of interest
Study I	Before-after	Questionnaires Audit data from 31 primary care practices	Adaption of the intervention Change in number of appointments due to BP, dyslipidemia and diabetes Change in treatment levels
Study II	Modelling study	Audit data from Study I	Approximation of time used for BP measurements and lifestyle counselling
Study III	Controlled before-after	National prescription register: Antihypertensives issued by 25 facilitator GPs and 53 control GPs	Changes in use of antihypertensive drugs according to CC guideline
Study IV	Follow-up of a RCT	Chart audit of 150 patients	Levels of CV risk factors

BP = blood pressure, CC= Current Care, CV= cardiovascular, GP = general practitioner, RCT = randomised controlled trial.

4.1 Setting

Studies I, II, and III were carried out in a primary health care setting in Helsinki, the capital of Finland. At the time of the study the population of Helsinki was approximately 560 000 (Table XI). The Helsinki health centre comprised of seven health districts with all together 31 primary care practices (PCP), staffed by 292 doctors and 560 nurses. Practices were arranged through the 'personal doctor' system. The coverage of primary care centres in Finland (i.e. the percentage of city's inhabitants using primary care services at least ones in a year, including maternity and child health clinics and school health care) was 66.5% in whole country in 2002. The respective figure for Helsinki was 48.1%.

In Study III two large cities were selected as controls (Table XI). The 'Personal Doctor' system was used in Turku whereas in Kuopio the conventional system was used. The coverage of Kuopio and Turku in 2002 was 86% and 56%, respectively.

Study IV was conducted in one PCP in a suburban area in Northern Helsinki. The population of the area had grown from 11 000 at the intervention time to 12 000 at the follow-up time. The coverage was approximately 47% (16).

Table XI. The population of Helsinki, Kuopio and Turku in 2002 and 2003

Age	Helsinki 2002	Kuopio 2002	Turku 2002
<18	98322 (17.6)	19477 (20.9)	29820 (17.1)
18–64	386068 (69.0)	60696 (65.0)	116055 (66.5)
>64	75326 (13.5)	13141 (14.1)	28744 (16.5)
Total	559716	93314	174619

Source of information Sotkanet indicatorbank (1)

4.2 Intervention (I–III)

The Helsinki Prevention Programme was a multifaceted facilitated intervention carried out in Helsinki Health Centre in 2002–2003. The aims of the programme were

1. to enhance the recognition of CV high risk patients and direct these patients to care,
2. to agree on task division between different health professionals (especially between doctors and nurses),
3. to enhance the adoption of Current Care guideline recommendations and EB health care.

The programme comprised of four core processes: education, audit, guideline and information. Interventions were oriented toward professionals and organisation, and indirectly towards patients (TableXII). In addition the intervention included financial component. At the organisational level interventions were targeted at three professional levels. Facilitators, a voluntary doctor-nurse pair, recruited from each PCP, played a central role in the programme. They attended an intensive two-year training course, performed the audit process in the practices, and tailored drafts for the local guidelines. Furthermore at their own practice, for their peers, they acted as change agents (internal facilitators) facilitating change in clinical practices towards the goals of the programme.

Table XII. Helsinki prevention programme, different components and target groups.

Target group	Components of the intervention
Management	**Audit and feedback** (O, Pr) **Facilitation**: consensus meetings (O, Pr) **Local guidelines** (O, Pr) **Marketing** (start event, reports, publicity) (O, Pr)
Facilitators	**Audit and feedback**, benchmarking (O, Pr) **Education** (Pr), consensus building (O, Pr) Incentives and rewards (F) **Local guidelines**, development (O, Pr) Networking with peers, communication (O) and with city's departments (O)
GPs and nurses	Audit and feedback (Pr) **Education**, general (Pr) **Facilitation**: consensus meetings, education, communication (O, Pr) Health checks (Pr) **Local guidelines**, distribution, reminders (O, Pr) **Marketing** (start event, publicity) (Pr) Working tools (Pr, P) Self-measurement places (O) Task dividing (O)
Patients / population	Events (P) **Marketing** (publicity) (P) Self-measurement places (O) Patient material (P)

F= financial, O= organisational, Pr= professional, P= patient / population. The main components are in bold type.

The education for the facilitators, described in detail in Figures 3 and 4, included 16 different sessions lasting from 2 days to 2 hours (total 84h), distance learning tasks (67h, n=12), literature (40h), and organising education at their own practices (24h). The education was multiprofessional as GP and nurse facilitators were together in the sessions. Furthermore depending on the subject, physiotherapists, dieticians, and physical-education instructor attended the sessions. The themes of the educational sessions were: facilitation skills (motivation, team dynamics, quality tools, process of change), clinical issues on CVDs, EBM, CC guidelines, and computer skills. Interactive methods were mainly used.

The audits are described in detail in the section 4.3 Process evaluation, structure and process measures (I).

The local guideline process was started with careful familiarisation of the CC guideline. In small group workshops the facilitators drafted outlines for local guidelines. The outlines were then presented to the whole group of facilitators and different options were discussed. One draft was selected and relevant parts from others were added. The project manager and assistant further revised the draft. Comments from management and co-workers as well as from national CC guideline working group were obtained. The final local guideline was used in educational sessions and consensus meetings in practices, placed in the intranet and printed as posters.

The information process included marketing at the management, staff, and population levels. It consisted mainly of start event, reports, and feedback from audits. The main aim was to increase commitment and guarantee personnel and other resources. Moreover articles in the Health Centres own publication, national newspapers, and professional publications were published. The project was presented to health professionals at several lectures. The project manager was interviewed on television and radio.

4.3 Process evaluation, structure and process measures (I)

The attendance of the facilitators to the educations was recorded and the facilitators reported the number of education sessions at PCPs each year. The process evaluation and changes in structures were carried out in three different self-evaluation questionnaires.

After the first year of the programme (1/2003) and near the end of the programme (9/2003) facilitators organised a questionnaire surveying the attendance to the programme (scale 1–7; 1=not at all, 7=a lot), realisation of task division (yes/no), use of produced working tools (yes/no), use of self measurement places (yes/no), and the advantages of and barriers to the programme were surveyed (open-ended questions) (Appendix I). The outcome measures for the adoption were facilitators' attendance (%) to the education sessions, self-evaluation of prevention work, number of facilitated sessions at practices, and the five main advantages and barriers of the intervention.

In a questionnaire (9/2003) facilitators, head doctors and head nurses evaluated the awareness of the 'prevention eye' in doctors, nurses and in the whole PCP (scale: Finnish 'school grade' 4–10). The 'prevention eye' was defined as improved prevention and treatment according to the national guidelines; enhanced multiprofessional teamwork and task division in the care of lifestyle diseases; improved screening, total risk evaluation, and empowerment of patients. The outcome measure was the mean for the 'prevention eye' for facilitators, head doctors and head nurses.

The changes in treatment processes were measured in one-week clinical audits on BP measurements, and dyslipidaemia and diabetes patients. For each subject a baseline and one-year follow-up audit was performed. The data was collected as cross-sectional manual audits during appointments. The facilitators, provided with instructions and audit sheets (examples Appendices II and III), organised the audits at their own PCPs. Every available nurse (BP audit) and doctor and nurse (diabetes and dyslipidaemia audits) doing outpatient consultations during the audit kept simple records: the total number of specific patients at appointments, and categorised value of blood pressure, lipids and Hb-A1c levels, and other topic specific measures. The patients were categorised as being in good, moderate or poor

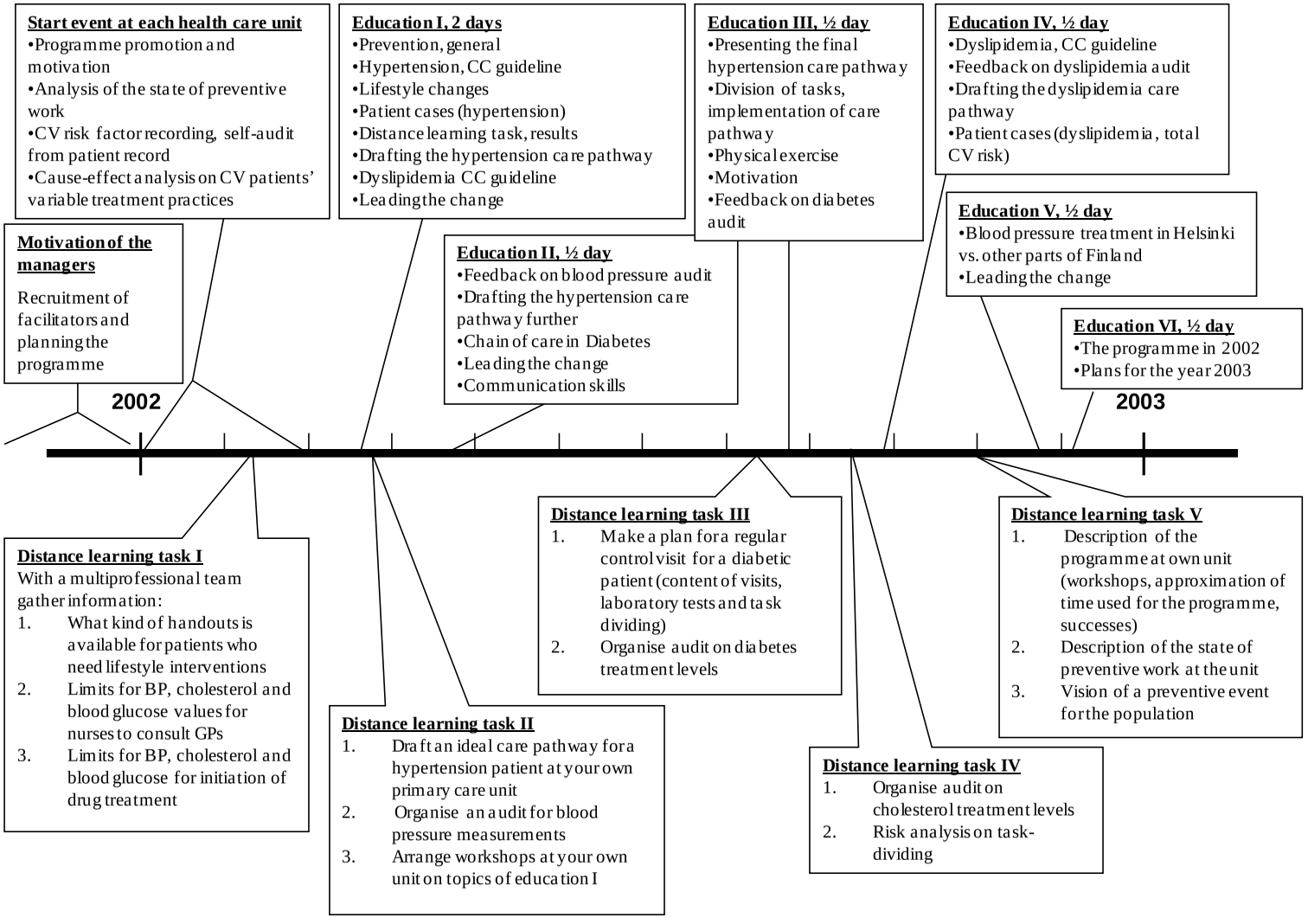

Figure 3. The detailed description of the educational process for the year 2002. Study III, Figure 1, p.3

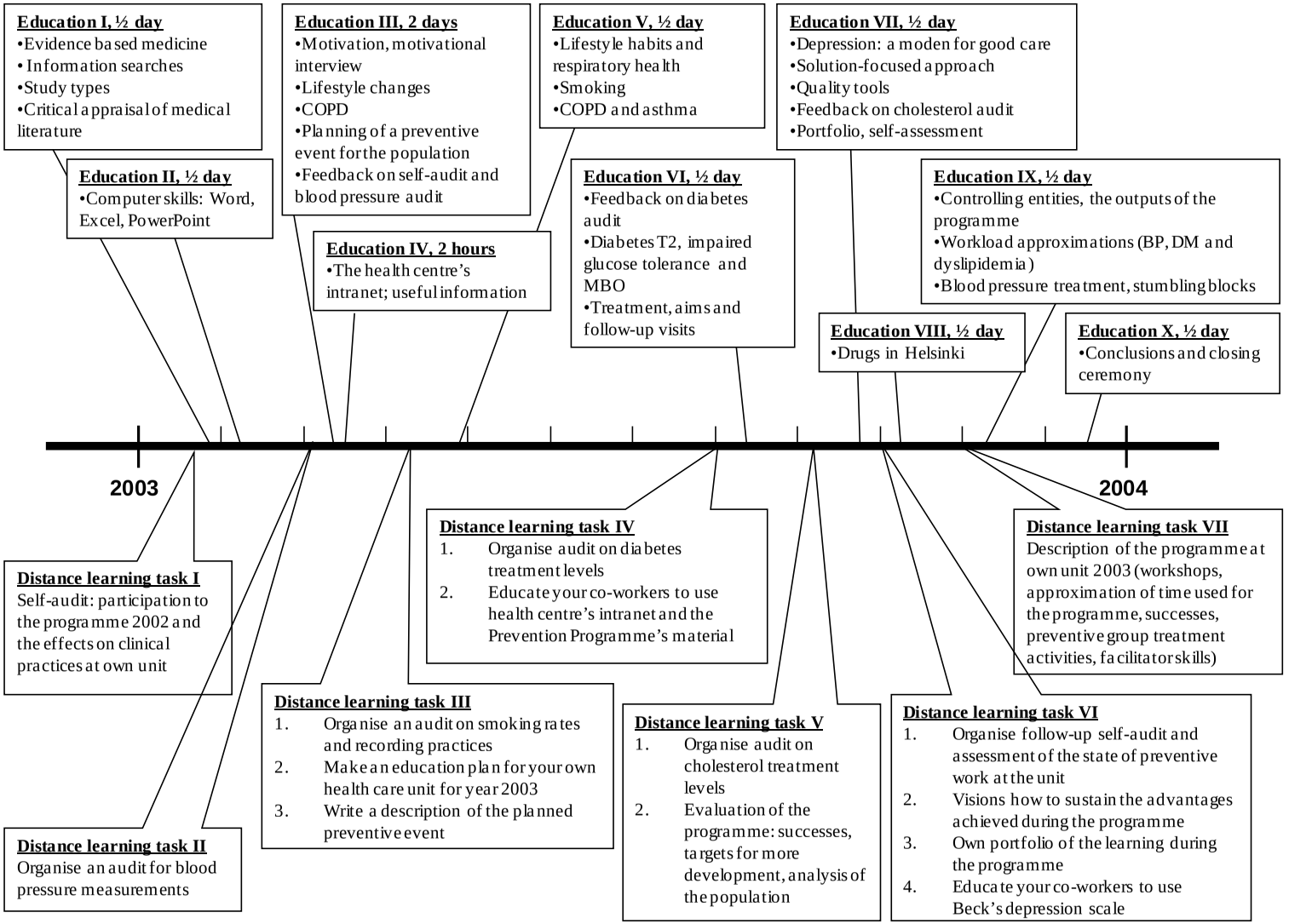

Figure 4. The detailed description of the educational process for the year 2003.

control (for the specific definitions see Study I, page 35). The higher blood pressure figure (systolic or diastolic) determined how the measurement was classified, and for dyspidaemia and diabetes the latest laboratory values in the patient records were used. The main outcome measurements were the total number of patients in each audit and number and percentage of patients in each treatment level category.

4.4 Workload (II)

The same audit data from Study I was used in this modelling study. Approximations of allocated time for BP measurements and for lifestyle counselling before intervention and at the one-year follow-up were calculated. It was assumed that all nurses conducted a mean number of BP measurements during every week of a year and had standard working hours as well as four weeks' vacation.

The allocations for lifestyle counselling (Table XIII) were based on the Current Care guidelines, and on other recommendations for preventive activities. The main outcome measurements were the time allocated to BP measurements and lifestyle counselling for those nurses attending the audit and extrapolated to all nurses working in the health centre.

Table XIII. The time allocations for blood pressure (BP) measurements and preventive guidance.

	Estimated time (min)				
BP level	**BP measurement**	**Antismoking counselling***	**Counselling on physical activity**	**Diet counselling**	**Total**
Good	7	-	-	-	7
Moderate	7	3	4	8.20	22.20
Poor	7	3	4	8.20	22.20

*22.8% of the patients were found to be smokers (based on a smoking rates audit, unpublished observation) and were thus given antismoking counselling.

4.5 Prescribing practices (III)

4.5.1 Subjects

From the 31 facilitator GPs 25 gave consent to data collection related to their prescriptions. Two contact persons recruited voluntary controls and 53 GPs gave their permission.

A patient was defined as a study patient if he or she had purchased certain reimbursed antihypertensive drug prescriptions issued by a facilitator or a control GP during the study period (1st January to 31st March 2001 or 2003).

4.5.2 National prescription register

The prescribing data was retrieved from the National Prescription Register managed by the Social Insurance Institution (SII). The register has been established in 1993 and it includes all medication purchases with direct reimbursement upon purchase at a computerised pharmacy. The register data is collected monthly from the pharmacies. Both patients and doctors can be identified by their personal IDs. The data includes patient-specific data, and prescriber, drug and pharmacy data. The drugs are classified according to the global Anatomical Therapeutic Chemical (ATC) system. Information on the indication of the drug is recorded in a non-systematic way in the register but is available in the complementary Special Reimbursement Register in case the patient is entitled to Special Reimbursement due to a chronic condition. [97] Reimbursement is divided into Basic (50%) and Special Reimbursement, and the Special Reimbursement further into Lower (75%) and Higher (100%) Refunds. In order to be entitled for Special Reimbursement for specific medication costs, the patient must fulfil the diagnostic criteria for the corresponding illness and submit a physician's certificate. In some conditions, for example diabetes, there are time limitations for conceding the Special Reimbursement. At the study period all antihypertensives were approved for Basic Reimbursement.

4.5.3 ATC codes

The ATC system, created by the WHO Collaboration Centre for Drug Statistics Methodology, groups the drugs at five different levels according to the organ or system on which they act and their chemical, pharmacological, and therapeutic properties. The first level indicate the main group, the second level pharmacological/therapeutic subgroups, the third level and fourth levels chemical/pharmacological/therapeutic subgroups and the fifth level is the chemical substance. (17)

4.5.4 Patient's antihypertensive medication

The data was drawn from the register for a three-month period before the first year of the intervention, 1st January to 31st March 2001, and the respective period in 2003, after the first year of the intervention. Irrespective of the refund category (Basic or Special Refund) the included prescriptions were miscellaneous anti-hypertensives (ATC code C02), diuretics (C03), beta-blocking agents (C07), calcium channel blockers (CCBs) (C08) and agents acting on the renin-angiotensin-aldosterone system (RAAS) (C09). Dispensations were converted to represent the drugs used by each patient. The conversation included two steps: combination drugs were recoded into separate chemical subgroups (third ATC level), and duplicate purchases were deleted (second ATC level) (Study III, Figure 2, p.5). Detailed examples of inclusion in and exclusion from the medication list are presented in Figure 5.

4.5.5 Main outcome measures

The main outcome measures were: 1) the proportion of patients treated with two or more concurrent antihypertensive drugs, 2) the proportion of patients with CHD treated with beta-blocking agents, 3) the proportion of patients with diabetes treated with RAAS, and 4) the proportion of patients with hypertension only treated with diuretics. The results were reported separately for the hypertension patients with 1) hypertension only (no purchases of antidiabetic agents (A10) and under the Special Refund for CHD), 2) CHD (purchases under the Special Refund for CHD but not for antidiabetic agents (A10)), and 3) diabetes with or without CHD (purchases of antidiabetic agents (A10)).

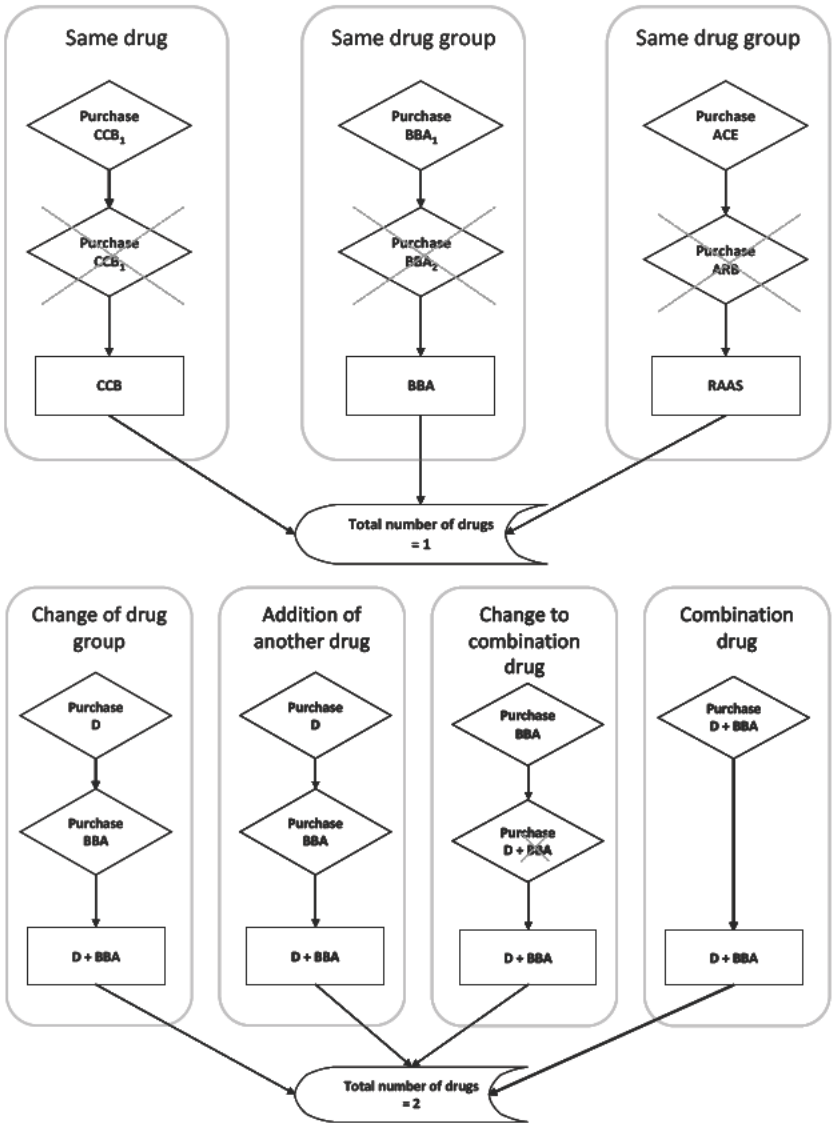

Figure 5. Examples of purchases converted from Prescription register data into medication list.

ACE = angiotensin-converting enzyme inhibitor, ARB = angiotensin II receptor blocker, BBA = beta-blocking agent, CCB = calcium channel blocker, D = diuretic, RAAS = agent acting on rennin-angiotensin-aldosterone system. Crossed lines = deleted from the list.

4.6 Long-term follow-up of lifestyle intervention (IV)

The study was a long-term follow-up of a two-year personally tailored multifactorial and multiprofessional randomised, controlled intervention study [157]. Initially the inclusion criteria were age of 18–65 years and high CVD risk score (modified North Karelia project's cardiovascular risk score ≥4.5). The risk score described the additive risk of six CV risk factors: systolic and diastolic BP (each 1–2 points), BMI (0–2), total cholesterol (0–4), smoking (0–4), and physical activity (0–2). Other inclusion criteria were willingness to participate in the study for two years, spoke Finnish, had no other severe diseases (systemic or psychiatric illness), and was not pregnant. GP tailored the intervention according to patient's risk factor profile, needs and present motivation to make lifestyle changes. For all the intervention included booklets on healthy lifestyle and diet counselling (nurse). Other interventions (described in detail, appendix IV) were diet counselling by a dietician if BMI was 35 or over (n=8), weight-reduction group (n=1), tobacco cessation group (n=20), and physical exercise programme (physiotherapist) (n=21). If treatment goals according to guidelines were not achieved CVD medication was added. The controls received standard care by their own GP and a booklet on healthy lifestyle.

The intervention patients (n=75) met a nurse and a doctor and risk factors were measured at baseline, and at 6, 12 and 24 months. The controls (n=75) were seen at baseline and at 24 months. At baseline the mean risk score in intervention group was 5.7 (Table III, Study IV) and 72% had an existing CVD, of these over two-third had solely hypertension. In the control group mean risk score was higher 6.5, 68% had CVD, but only two patients any other CVD than hypertension. In the original study, sample size was calculated to detect a 1.2 point difference in the means of risk scores with a 90% power.

The follow-up was a chart audit from both electronic and conventional paper patient records; both structured records as well as free text notes were used. The latest data on systolic and diastolic BP, total cholesterol, blood glucose, weight, height, smoking status, all cardiovascular morbidities and new cardiovascular morbidities eight years after the beginning of the intervention was collected. In addition the number of GP consultations was calculated. Those patients moved from the area before the introduction of EPR (2002) were lost to the follow-up.

The main outcome measures were the treatment levels of risk factors (blood pressure, mmHg; total cholesterol, mmol/l; body mass index, kg/m^2; weight, kg; blood glucose, mmol/l; smoking rate, %) and the mean net change in risk factors.

4.7 Statistical analysis

Means were calculated in the self-evaluation questionnaires when appropriate (I). A change of practice was regarded as having occurred if half the personnel of a PCP in the audit had indicated the change. For clinical audits number and percentage of patients in each treatment level was calculated (I) and for percentages of patients at each treatment category 95% confidence intervals (CI) were calculated (II).

The use of specific antihypertensive agents and the use of two or more concurrent antihypertensives after the intervention was compared with the situation before in each patient group, adjusted (age and gender) odds ratios (ORs) were estimated using logistic regression (III). The 95% CIs were calculated. The statistical significance of the difference in the ORs between the groups was estimated by including an interaction term between time (after versus before) and group (intervention versus control) in the model. The clustering of patients by physician was considered using generalized linear mixed models in the estimation. Therefore physician acted as a random effect.

A *t*-test was used for comparing means of continuous variables and the chi-square test for the frequencies between the two groups (IV). Intragroup analyses were performed with McNemar's test.

Statistical analyses were made using SPSS for Windows version 15.0 (Studies III–IV) and SAS 9.2 (Study III). P values less than 0.05 were considered statistically significant.

4.8 Approvals

All the data in the thesis is either register data or clinical unidentifiable patient data collected at the appointment. Finnish law allows the use of register data for research purposes with authorisation from the register controller. Therefore permission was obtained from the Helsinki Health Centre (Research coordination group) (I, II and IV). The Health Centre requested approval from an Ethics committee for a part of the study not included in this thesis. The study was approved by the Ethics committee of Helsinki and Uusimaa Hospital District (Epidemiology and Public health) and regarded as quality study rather than a clinical study. For prescription data permission was obtained from the SII (III). In addition facilitator and control GPs gave their written consent (III).

5. RESULTS

5.1 Process evaluation, process measures and workload (I–II)

During the Helsinki Prevention Programme local guidelines were developed for elevated BP and dyslipidaemia, and gestational diabetes. In addition a model for yearly control for diabetics was developed. Further a set of educational material (slides, brochures, working tools) was produced and available to the health centre's staff.

The attendance rate of the facilitators to the educational sessions was 86% in 2002 and 76% in 2003. The response rate to the distance learning tasks was 97% for both years. The mean number of educational sessions organised by facilitators at their own practices was 5 (range 1–6) along with several discussions at professional meetings.

5.1.1 Self-evaluation

After the first year of the programme (respondents n=512, 64%), mean participation (scale 1–7) to the programme was 3.5 (range 1.3–5.8) and at the end (n=425, 53%) 4.3 (2.8–5.6); most committed were nurses, followed by doctors and other personnel. Self-reported change in task division and the use of local guidelines was high especially for BP and increased for diabetes and dyslipideamia in the second year (Table XIV). The main advantages of the programme were mutual clinical practices ('house rules' and improved recording) (n=31), clarified task division and multiprofessional care (n=31), new knowledge and working tools (n=13), enthusiasm and motivation to work (n=9). In addition self-measurement places were mentioned in nine answers. The mutual practices often included goal-orientation, and besides professional roles task dividing considered patient's role, empowerment and self-care with diminished pressure on professionals. On the other hand the most often mentioned disadvantage was a lack of time and the time consuming activities of the programme such as audits and total risk assessment of a patient (n=23). The workload had increased especially in the beginning when new practices were implemented (n=10). Over half of the answers stated that the programme had no disadvantages (n=18).

The development of a 'prevention eye' for PCPs was evaluated higher by head doctors and nurses than facilitators. The mean for awareness of a 'prevention eye' was 8.5, 8.6 and 7.9, respectively.

Table XIV. Number of PCPs reporting change during the programme (self-reported).

	First year	Second year
Changes in task division and work content		
hypertension patients	20	29
diabetes patients	7	25
dyslipidemic patients	8	22
Use of the Helsinki Prevention Programme materials		
local guideline on elevated blood pressure	16	31
local guideline on diabetes	3	25
local guideline on dyslidaemia		22
Active guiding of patients to		
home measurements	28	31
self-measurement places	15	31

5.1.2 Clinical audits and workload

The number of BP measurements diminished in the follow-up and shifted toward patients with poor treatment balance; the increase in the proportion of patients with poor treatment level at appointments was 4.9% (Table XV). At the same time the difference between the practices increased, the range for poor control was in 2002 from 14.5% to 19.3%, and in 2003 from 14.0 to 30.9%, respectively. Changes were similar in diabetes audits for both GPs and nurses but opposite for dyslipidaemia, especially for GPs (Table XVI).

The approximated mean number of BP recordings per nurse per week was 18 in 2002 and 9 in 2003 corresponding to 487 000 and 250 500 measurements in a year, respectively. If BP measurement and lifestyle counselling accompanying the measurement was performed according to guidelines, the audited time for this work would have diminished in the follow-up from nearly 800 hours to 600 hours (Table XV). When extrapolated to the whole city, the time for these preventive activities would have nearly halved (Figure 6) still requiring 36 nurses (66 in 2002) only measuring and counselling.

Table XV. Number and percentage (95% CI) of BP measurements falling into different categories and weekly time allocated to preventive actions* in 2002 and 2003.

	2002 Nurses n=172			2003 Nurses n=250		
BP level	**N**	**% (95%CI)**	**Time (h)**	**N**	**% (95%CI)**	**Time (h)**
Good	1214	38.9 (37.2, 40.6)	141.6	828	35.5 (33.6, 37.5)	96.6
Moderate	1371	44.0 (42.2, 45.7)	454.4	990	42.5 (40.5, 44.5)	330.7
Poor	534	17.1 (15.8, 18.4)	177.0	512	22.0 (20.2, 23.7)	169.7
Total	3119	100	773.0	2330	100	596.9

*Preventive actions: BP measurement and anti-smoking, diet, and physical activity counselling.

Table XVI. Audited treatment levels of patients with diabetes and dyslipidaemia in 2002 and 2003. Number (N), percentage (95% CI), and range in each category.

	2002				2003			
	N auditers	N patients	% (95%CI)	Range	N auditers	N	% (95%CI)	Range
Diabetes, GPs	122	410			161	560		
Poor		131	32.0 (27.4, 36.5)	24.7–40.4		200	35.7 (31.7, 39.7)	25.6–46.8
Diabetes, nurses	172	553			229	766		
Poor		172	31.0 (27.2, 35.0)	14.5–41.8		254	33.2 (29.8, 36.5)	17.7–51.4
Lipids, GPs	144	965			150	849		
Good		328	34.0 (31.0, 37.0)	20.5–48.5		368	43.3 (40.0, 46.7)	31.7–52.8
Moderate		491	50.9 (47.7, 54.0)	36.4–61.5		395	46.5 (43.2, 49.9)	40.3–53.5
Poor		146	15.1 (12.9, 17.4)	11.7–17.9		86	10.1 (8.1, 12.2)	6.9–17.1
Lipids, nurses	220	822			226	938		
Good		210	25.5 (22.6, 28.5)	7.8–36.8		284	30.3 (27.3, 33.2)	20.8–43.2
Moderate		512	62.3 (59.0, 65.6)	54.2–81.3		515	54.9 (51.7, 58.1)	45.5–67.7
Poor		100	12.2 (9.9, 14.4)	7.5–15.4		139	14.8 (12.5, 17.1)	11.4–17.6

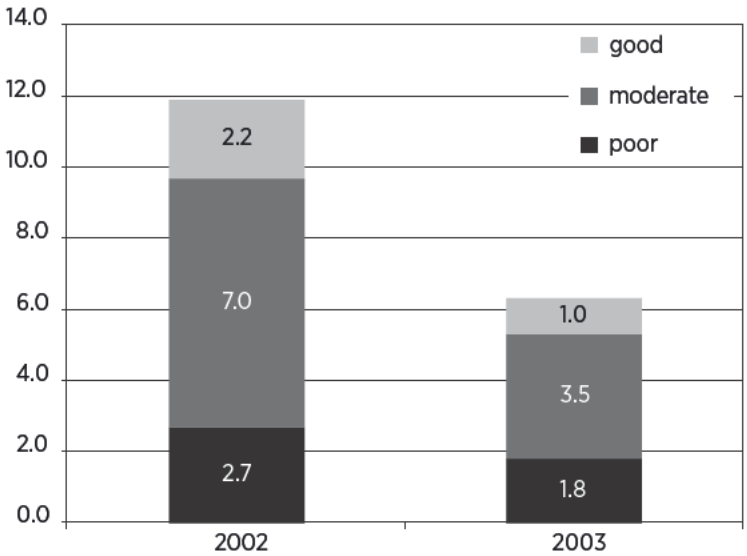

Figure 6. Allocation for nurses, extrapolated time (percentage of total working time) used for blood pressure measurements and lifestyle counselling for the whole city.

5.2 Prescribing practices (III)

5.2.1 Participants

Most of the intervention and control GPs were experienced and CVD prescriptions composed approximately one third of all prescriptions (Table XVII). A total of 2872 and 3865 patients of facilitator GPs and 7066 and 8693 patients of control GPs purchased antihypertensives in the study periods in 2001 and 2003. The intervention and control patients were fairly similar; median age 70–71 years, approximately two thirds over 65 years old, over 60% females. The proportion of patients with CHD in the intervention group was 11% both in 2001 and 2003. In this group 10.5% in 2001 and 12% in 2003 were diabetic patients. In both study periods in the control group 13% were CHD patients and 9% diabetics.

Table XVII. Characteristics of the facilitator and control GPs.

	Facilitators n=25	**Control GPs n=53**
Women, n (%)	22 (88)	22 (71)
Age, median (range)	40.0 (27–60)	43.0 (25–57)
GPs specialised in general practice	14 (56.0)	26 (49.1)
Working years in PC, median (range)	13 (1–25)	15 (1–30)
Mean n of CVD prescription in 2001	1 242	1 360
Mean n of all prescription in 2001	3 664	4023

PC= primary care; CVD prescriptions= antihypertensives (ATC C02, C03, C07, C08, C09), lipid modifying agents (C10), and drugs used in diabetes (A10). Prescription data was drawn from the National Prescription register and includes reimbursed purchases.

5.2.2 Prescribing

At baseline the mean number of concurrent antihypertensive agents did not differ between intervention and control patients (patients with only hypertension 1.5, CHD 1.4 and diabetes 1.7). Compared to the controls the proportion of patients who used two of more concurrent antihypertensive drugs was slightly smaller for intervention patients with only hypertension (-1.7%) and diabetes (-1.8%) but was higher for CHD patients (+3.7%). No significant differences in the change of proportion of patients with two or more concurrent antihypertensives between the groups were observed. However, the percentage of patients receiving two or more concurrent antihypertensives increased in all subgroups reaching statistical significance for control patients with only hypertension (+2.8% units, OR 1.13 (95% CI 1.05, 1.21; p=0.002)). Furthermore the change in intervention patients with only hypertension and diabetes approached significance (+2.4% units, OR 1.12 (0.99, 1.25; p=0.006) and +7.1% units, OR 1.33 (0.99, 1.79; p=0.006)).

At baseline for the main outcome measures differences between the intervention and control patiens were observed: the prescribing of beta-blockers was 6.8% lower for CHD patients and 6.2% higher for diabetic patients in the intervention group. CCB prescribing was more common for all intervention subgroups. There were no significant differences in the change in use of specific antihypertensives between the groups (p-values in intergroup comparisons >0.05). The use of beta-blockers and RAAS increased in all subgroups while the use of diuretics and CCBs stayed relatively unchanged or even decreased. The results for the main outcome measures are presented in Table XVIII. For the intervention group the use of beta-blockers increased by 6.1% units (OR 1.39 (0.99, 1.96; p=0.06)) but the baseline use was low compared to controls. Similarly in the controls the use of RAAS for diabetes patients was low at the baseline (46.4%) and increased significantly (+5.2% units, OR 1.27 (1.02, 1.57; p=0.03)).

5.3 Long-term follow-up of lifestyle intervention (IV)

Medical records for 19 patients (12.7%) were not available. Therefore the follow-up chart audit was performed for 68 intervention and 63 control patients. For the intervention group the risk factors were quite well recorded (81–76%) while for the controls the recording was low for some risk factors (81–46%). No statistically significant differences in risk factor levels were found (p-values >0.05). However, the mean BP was 4.3/3.0 mmHg lower for the intervention group than for the controls. In the intervention group mean systolic BP had decreased during the intervention (from 147 to 141 mmHg) and thereafter stayed relatively unchanged (142 mmHg, p=0.06). For both groups the trend for diastolic BP was decreasing. Mean diastolic BP fell in intervention group from 91 mmHg to 89 mmHg during the intervention and further to 87 mmHg after the follow-up (p=0.002). For controls the figures were 95, 92 and 90 mmHg (p=0.03), respectively. Cholesterol fell from 6.1 to 5.1 mmol/l in the intervention group (p<0.001) and from 6.1 to 5.3 in control group (p<0.001). At the end of the intervention CV medication was used by 45 patients in the intervention and 35 in the control group. In the follow-up in both groups only two more patients had CV medication recorded.

Table XVIII. Number and proportion of patients who used specific antihypertensive drugs and adjusted odds ratios for change (main outcome measures study III, detailed results Table IV, p. 8).

	Intervention				Controls				Intergroup Comparison	
	2001	2003	Adjusted* OR (95% CI)	p-value	2001	2003	Adjusted* OR (95% CI)	p-value	Adjusted** OR (95% CI)	p-value
	n (%)				n (%)					
Hypertension, N	2250	2969			5504	6717				
Diuretics	886 (39.4)	1143 (38.5)	0.97 (0.86, 1.08)	0.56	2207 (40.1)	2575 (38.3)	0.92 (0.85, 0.99)	0.02	1.06 (0.92, 1.21)	0.44
CHD, N	320	440			950	1148				
Beta-blockers	235 (73.4)	350 (79.5)	1.39 (0.99, 1.96)	0.06	762 (80.2)	932 (81.2)	1.13 (0.90, 1.42)	0.29	1.25 (0.83, 1.88)	0.29
Diabetes, N	302	456			612	828				
RAAS	159 (52.6)	249 (54.6)	1.08 (0.80, 1.45)	0.64	184 (46.4)	427 (51.6)	1.27 (1.02, 1.57)	0.003	0.85 (0.59, 1.23)	0.39

Prescription data was drawn from the National Prescription Register during a three-month period in 2001 and 2003.

Abbreviations: RAAS, renin-angiotensin-aldosterone system; CHD, coronary heart disease; OR, Odds ratio; CI, confidence interval.

*Within-group analysis: Logistic regression, random effects model (physician as a random effect). Adjusted for patient's age and patient's sex.

**Intergroup analysis: Logistic regression, random effects model (physician as a random effect). A product term between time (after versus before) and group (intervention versus control) was added to the model. Adjusted for patient's age and patient's sex.

6. DISCUSSION

During the Helsinki prevention programme an internal facilitator network was established and in that way QI structures were offered for the organisation. The extensive programme enhanced multiprofessional communication and care, and developed treatment processes for CVD patients. CC guidelines were implemented as practical and feasible flow charts including the division of tasks. With new divisions of tasks and focus on prevention it was possible to target resources for those needing services.

6.1 Intervention (I–III)

The main components of the intervention were facilitation, education, audit and feedback, local guideline development and marketing. Facilitation in this intervention was internal with facilitators from the facilitated PCPs and executed by a team of peers of one GP and one nurse from each practice. This approach is rare. In the literature review only two studies used GP facilitators partly [49, 229] and one used partly internal facilitators [190]. It is evident that our approach has both pros and cons.

In organisational development theory the organisational development practitioner (i.e. the facilitator) can be internal or external. According to the theory entering into facilitation is easier for an internal facilitator than external one because the organisation, its persons, and group dynamics are familiar. [46] Another advantage is that the facilitator gains advantages for his own clinical work. The other side of the coin is that it may be hard to stay objective and not to pursue one's own aims at the expense of the organisation's or programme's aims. Additionally the facilitator may need to work harder to earn the new position in relation to his peers and even to the management. It is not self-evident, however, that an external facilitator will be regarded as trustworthy. The prestige of an intrinsic facilitator may especially be linked to his profession and its hierarchy [46] therefore it may have been a good choice to have both a GP and nurse acting as facilitators.

Intensive facilitation is time consuming, including facilitated session or visits, planning of the sessions, administrative work, and in the case of external facilitation, travelling. The essential, planning of sessions and facilitation itself, may make up only half of the external facilitators time [12]. In intrinsic facilitation it is possible to concentrate on one practice; the facilitator is easy to approach and is at the practice all the time. In this way the facilitator can more intensively support the

team in reaching its goals and dedicate himself to facilitation instead of using his time travelling. However, being present can lead to a situation where it is difficult to withdraw from patient appointments.

The individual facilitator's characteristics and group skills are said to be important for the success of the intervention. Petrova et al. identified three types of facilitators with different intensities of facilitation: a proactive driver of practice change, partner in practice change, and available with minimal effort if he is wanted [230]. We did not collect systematic field notes on facilitation but after each year the facilitators assessed the time used in programme activities. The devotion of the facilitators and intensity of the intervention to the practices seems to have varied greatly. Facilitator pairs reported to have used from 10 to 160 hours per year time in the project (training sessions excluded). Furthermore because facilitators need special skills [240] the education of the facilitators was extensive and it continued during the two programme years (in total 215 h corresponding to 29 work days, nearly 6 weeks). In one other programme intensive training lasted for 30 weeks and the next most comprehensive programme described in the literature was 80 hours [93, 94, 175]. However simultaneity of the facilitator education with intervention at practices could have weakened the facilitation effect.

The intervention was mainly directed to the organisation and professionals and only indirectly to patients, but it is difficult to clearly separate these parts from each other. Together with the facilitation, the main components of the intervention were education and local consensus (facilitators and practices), development of local guidelines, audit and feedback, and marketing. These methods should be effective in changing clinical practices [12, 109]. The educational sessions in practices were multiprofessional analogous to the facilitator education. There is some evidence that in purely educational interventions participants from single discipline may correlate positively to effect size [187] but in education accompanied by consensus building and quality improvement interdisciplinary is a necessity. Interprofessional guideline implementation has been rare in Finland [198] and a need for more emphasis on effective interprofessional collaboration has been expressed [140, 174]. Indeed more such activities are needed when redesigning treatment of chronic diseases in primary care.

Different from other interventions the local guidelines were developed by the GPs and nurses involved in patient work in the target organisation rather than by an external board [221, 250, 269, 297–299]. Furthermore the ownership and commitment was increased by the staff and managers' opportunity to comment on the drafts. The strength of flow charts compared to narrative guidelines is that the format helps to see sequential tasks [25]. The electronic flow charts included, in addition to EB diagnosis and treatment, task division when relevant and more detailed directions on content and recording to facilitate process change. Laminated posters of these flow charts acted as reminders as well.

Implementation and QI interventions face barriers that are related to the innovation itself, adopting person, organisation and socio-political environment [79]. Table XIX summarises how these barriers were tackled in the Helsinki Prevention Programme. How successfully these barriers were tackled is discussed in the results section of each study.

Table XIX. Barriers for innovation uptake according to Fleuren et al. [79] and interventions designed to deal with them in the Helsinki Prevention Programme.

Innovation (Guideline) Complexity, ownership, applicability	• **Facilitation,** consensus building • **Local guidelines,** development, consensus building, available in intranet and posters • **Marketing** • Working tools
Adopting person Knowledge, attitudes, skills	• **Audit and feedback**, benchmarking • **Education** (facilitators, practices, general) • **Facilitation** and consensus building, communication • Health checks • **Local guidelines** • **Marketing** • Networking with peers • Working tools
Organisation Leadership, change management infrastructure, support from peers, resources	• **Audit and feedback** • **Facilitation** • **Local guidelines** • **Marketing** • Self-measurement places • Task dividing • Working tools • Incorporation of programme aims to strategy
Socio-political context Economic and political decisions, secondary care, patients' attitudes	• Events • **Marketing** (internal and external publicity) • Self-measurement places • Patient material • Working tools

Both facilitation and outreach visits have been argued to be expensive [41, 92, 93, 136]. The costs per practice in these varying interventions have been from a couple of hundred US dollars or euros [41, 94] to approximately 4500 euros or more [176, 178, 179, 200]. However, the estimated cost savings of an extensive intervention (costs 240 000 US Dollars, length 12 months, 22 practices) overran the costs of the intervention and induced changes [134]. The budget of the two-year programme was 303 000 € equivalent to 4900 € per practice per year while the budget for the Health Centre was several hundred million euros. This included all costs of the project organisation, invectives for facilitators, and facilitator education. The budget did not include the work of the facilitators nor the time they spent for their own education. However, the facilitators were salaried and their input was just partly channelled to essential development of the organisation. In exchange the organisation gained an extensive CME programme for 62 professionals, a network of skilled facilitators, and structures of continuous QI.

A programme always has an end and therefore sustainability is always a challenge. Therefore at the end of the programme an action plan was made. The most important

suggestion was to maintain the established facilitator network. To ensure continuity a pair of facilitators was selected to act as hosts of the network but due to the lack of supporting structures, coordination and leadership the function deteriorated as has been seen in other interventions [9, 132]. In 2006, the Helsinki Health Centre joined the Rohto network. The Centre for Pharmacotherapy Development ROHTO was an expert unit under the Ministry of Social Affairs and Health (2003–2009) and since 2009 under the National Institute for Health and Welfare. The Rohto-centre promotes rational pharmacotherapy and supports implementation of this in practice. The unit educates local facilitators to run interactive multiprofessional workshops on rational pharmacotherapy and treatment processes in primary care [126]. The local facilitators are GPs and in some health centres pairs of GPs and nurses. The centre provides basic education and thereafter ongoing education and materials. Facilitators are further supported by a regional facilitator who also coordinates local activities. The facilitator pair system was continued in Helsinki and approximately two third of the original Helsinki Prevention Programme facilitators joined the new network and new facilitators were appointed for the remaining PCPs. The process development activated again with a strong commitment from Helsinki Health Centre's management. Now, nearly ten years later, about half of the original facilitators are still active (18). Of the other half, only a few have stepped aside from development work and some have retired. Many, however, have proceeded with their careers and exploited their knowledge and skills in managerial or development tasks. It may be concluded that the Helsinki Prevention Programme formed a solid basis for the organisation's quality culture but it seems that facilitation needs strong leadership and coordination to be functional. The programme was local and would need national steering if were implemented widely in primary care.

The intervention was an implementation intervention as well as a QI initiative. According to Donabedian's model quality of care can be measured from three viewpoints: structure, process, and outcomes [62]. Structure of care refers to setting and resources that are needed to provide medical care, process of care refers to the activities between health care professionals and patient, whereas outcome refers to the change in a patient's health status. The interventions first aim was to change processes and therefore mainly process measures were used. Structural changes were made to achieve process changes, and therefore structures were also measured. Outcome measures were used as well but more as a proxy of the process. The follow-up time of one year was considered to be too short to detect important changes in outcomes.

6.2 Methodological considerations

The randomised controlled trial is a golden standard for demonstrating the effects of an intervention and would be ideal to confirm the internal validity of a study because other study types are more susceptible to bias and errors. The intervention was done in a "real life" setting as opposed to a study done in a purely scientific context. It was a complex intervention with several integrating components in a complex setting of primary care. This kind of programme needs careful planning and evaluation [45]; causal relations between complex interventions and outcome measures are unsure and replication of the intervention is problematic [222]. However, RCT is not feasible when the basis is the needs of an organisation and aim is to study routine medical practices. Therefore quasi-experimental, practical, designs can be used in QI and implementation interventions and indeed, the external validity and generalisability for the population, may be higher. But the results of uncontrolled before and after studies (I, II) may overestimate the effects of interventions and it is important to remember that it is impossible to rule out bias with confidence. The data collection methods, recording of audit forms during consultations (I, II), may have acted as part of the intervention. If controls were used, the audit could have had effects on their practices as well, and therefore reduced any difference.

The controlled before-after design was chosen to diminish bias in Study III where register data was used. However, it was not possible to control the possible other interventions the control GPs were exposed to. No power calculations were performed (Studies I–III) due to the practical design of the intervention. To give insight into clinical significance of the results confidence intervals for percentages (II) and ORs (III) were presented. However, under-powering the study (type II error) is possible, especially for smaller subgroups (III). Statistically significant change was observed in the control group (diabetics, 5.2% increase in RAAS). Because the baseline adherence was quite high, the absolute 5% increase in adherence may have been clinically relevant. Therefore it seems that the sample size for controls was sufficient to detect intragroup changes for subgroups.

A measurement, an indicator of structure, process or outcome, should be relevant to clinical practice, valid, reliable, sensitive, and available [138]. An indicator is valid when meeting the indicator is a better quality of care and the indicators measure what they are set out to measure. Validity can be further divided into content (based on scientific evidence), face (acceptable and credible), construct (context free), and concurrent (relation to golden standard) validity. An indicator is reliable and feasible when data is complete, accurate, consistent and reproducible.

Facilitation studies have been often done using questionnaires, interviews and chart audits. In Study I self-evaluations (questionnaires) were used. A valid questionnaire measures what it claims to measure. Our self-evaluations measured

intervention, attendance, changes in processes and structures, and barriers and successes. Both statements with categories, rating scales and open-ended questions were used according to what was being investigated. However a few concerns should be raised. Self-reports tend to overestimate the actual performance and respondents may misunderstand the questions. Especially reliability may be diminished due to low respond rate if the participants are tired due to the considerable number of surveys conducted these days. [24]. The advantage is that it is a quick and low cost way to gather lots of information [222]. Furthermore with open-ended questions it is possible to evaluate unexpected changes of the intervention. More frequent field notes would have given more information on facilitation and its contents. We defined process change at the practice level using the individual answers. A change had happened if half of the respondents indicated change. Another way of measuring change could have been the percentage of professionals indicating change at each practice.

The clinical audits (I, II) were based on evidence (guidelines) and therefore their content validity is high. However, attitudes towards audits may be negative; the measurements can be seen as picking up the bad apples instead of giving tools to improve practices. The time consuming way of recording audit forms during consultations was often mentioned as a barrier but the measurements seemed to be well accepted with an increasing number of auditors as the intervention proceeded. The treatment level was a surrogate of process not a pure outcome measure. The concurrent validity of measures is difficult to estimate due to the lack of golden standards for measuring the process and patient streams. The measurement is neither context free; guideline recommendations may change over time and the indicators should be updated. However the indicator can answer the question of whether medicine is properly practised according to our present knowledge. Outcome measures as such were not included because they need a longer period of follow-up and have more potential confounding factors [62]. Additionally the relationship between structure and process or structure and outcome is not often well established [62].

The self-collection of audit data exposes the research to some biases. Its reliability can be questioned due to possibility to select patients and manipulate results. Further the large number of auditors may lead to different interpretations. However, manipulation seems unlikely since the treatment levels deteriorated for BP and diabetes audits. Self-evaluations clearly indicated the need for automatic data collection from EPR and this would have been one method to minimize bias and interference with daily practice. The EPR was introduced to Helsinki Health Centre during years 2001–2002 and automatic data collection was not feasible at the time of the intervention. In cases of pure research an external auditor would have been one option.

The target group for the prescribing measurements was the facilitator GPs because they had the most intense intervention (III). It was assumed that if the facilitators did change their own prescribing practices they could possibly induce change in their colleagues' practices but in opposite situation the change was unlikely to happen. However, generalisability is not straightforward because the facilitators and controls were voluntary and experienced GPs and may, therefore, differ from the basic population of primary care physicians. The measurements were guideline based and drawn from the National Prescription register with high quality data [97]. In our cross-sectional data we included all antihypertensive prescriptions purchased during the data collection period. An alternative design would have been the strongest quasi-experimental design, interrupted time series, permitting to separate real intervention effects from other long-term trends and to observe both immediate and delayed effects [276]. Furthermore the use of only incident users of certain drugs would have given more valid information on the prescribing of specific drugs after the beginning of the intervention. The register data would have allowed us to use these approaches but both of them would have required longer follow-ups. Furthermore the cross-sectional data collection does not allow us to look for the discontinuation of drugs (Figure 5). The short three-month time-window, on the other hand, diminishes this bias. The shortcoming of prescription register data is, however, that it does not reflect solely doctors' behaviours nor does it give full insight into real use of drugs. Furthermore the use of reimbursement codes as a proxy for morbidity may not be specific.

Related to register data is always unmeasured confounding factors. We stratified the patients in three morbidity subgroups to increase the homogeneity and conducted adjustments by patients' ages and sexes. But information of other possible confounding factors, such as socioeconomic status and other co-morbidities were not available. The project was conducted in Helsinki, the capital of Finland, and the controls were from two large cities. Both intervention and control GPs were from various parts of the cities thus they did not represent certain types of areas with consequent clustering of socioeconomic characteristics.

We used random effects logistic regression, using physician as a random factor (III). In order to control for stable characteristics (including those we did not measure) of the participating physicians we also analysed the results using fixed-effect models. In this logistic regression models, there was an indicator variable for each physician (except for one). The fixed-effects estimates had larger standard errors than the random-effects estimates, while the p-values changed in both directions. The changes in ORs were minor (generally <5%) suggesting that these physician characteristics did not act as confounders. Our conclusions, however, would have remained the same.

Both conventional patient records and EPR were used as data sources (IV). This approach of routine medical practice was selected to support the practical research

design of Studies I-III and due to its low costs. The data used were diagnosis and examination findings and laboratory test results from both free text and structured data. The use of free text notes diminishes the accuracy and reproducibility of the data but gives more complete data. Furthermore one auditor increases the consistency of the recordings. In Finland the quality of recording has been found to be moderate to poor especially for examination findings and medication while diagnosis is more often recorded [268] although not necessarily in a structured way [160], whereas the results of laboratory tests are always linked to the EPR in a structural way. Clinical data would have been more reliable but possibly resulted in an even greater dropout rate.

6.3 Changing structures and organisational processes (I, II)

At least the following four structural changes were realised; a facilitator network, local guidelines, enhanced teamwork and self-measurement sites. The facilitators' high attendance at training sessions and high number of returned distance learning tasks indicate commitment to the programme as does the increasing attendance to the audits and self-evaluation of attendance. However, the implementation of the facilitation at the practice level varied. This finding is concurrent with previous research findings [12, 176, 230]. Presumably facilitator characteristics have had some effect, though a major barrier seemed to have been time constrains. Furthermore 31 practices were different, although parts of one organisation, and their baseline was different in relation to their readiness for change, staff relationships and stage of turmoil (for example staff turnover) [67, 68, 132]. A lack of leadership is a major barrier for committing time to a project and thus hinders change. It also worsens the working opportunities of the facilitator [67, 240, 281]. This barrier may, however, be difficult to report in internal facilitation.

Developed local guidelines were adopted and accepted. It seems that guideline related barriers – complexity and lack of ownership [85, 197] – were overcome. Developers being co-workers, adaptation to their own organisation and the description of professional responsibilities may have been the key factors of success. Local guideline adoption is considered to be an important facilitator of implementation although it is not enough [221, 241, 250, 269, 297].

Lack of interprofessionality and effective multidisciplinary teams is a major barrier for high quality care of chronic diseases [123]. The enhancement in interprofessionality was most prominently seen in self-evaluations. Such important factors of effective teamwork as mutual goal oriented care, clear roles, diminished overlapping work and increased self-care of patients [21, 117, 177] came up. And maybe most importantly working motivation and enthusiasm grew. Moreover, although there is not data on this, the evolving of teams was seen in the facilitator

training sessions in growing enthusiasm, the good atmosphere of the sessions and discussions as equals between different professions. D'Amour and colleagues defined interprofessionality as the development of an integrated and cohesive practice between professionals from different disciplines to answer the needs of the population and reflection of the practices [50]. Furthermore collaboration is a process that requires joint planning and negotiation [50] as the intervention offered at facilitator educations and at facilitated sessions. The pairing of a GP and a nurse involved both professions more deeply in the project and facilitated utilisation of viewpoints of both professions. Additionally it was a way to give a model of teamwork for the practices. Other facilitation studies have also seen it is possible to improve teams with facilitation [39, 136, 178]. It may also be difficult to enhance teamwork if the intervention is offered to one leading physician and practice manager whose styles are didactic and the facilitator practice visits are more data collection than consensus building [216].

The self-measurement sites further supported teamwork. This low cost innovation was implemented at every PCP with success, and the sites were successfully sustained in the organisation. The sites offered patients knowledge of CVDs and clinical practices, and an opportunity to follow their own BP without investing in their own sphygmomanometers. Similarly simple structural changes have been implemented in facilitated interventions, such as registers [49, 136], but these depend on the stage of computerisation and baseline adherence [136, 178]. In addition, even larger structural changes that require resources, for example separate clinics, have been implemented [178].

The results for process measures in facilitated interventions have been mixed (Table VIII). In our study in the clinical audits mean number of BP measurements per nurse decreased markedly from 18 to 9 and resources were targeted to those with poor treatment levels. An important facilitator of change may have been the self-measurement sites which were actively used [261]. Additionally measuring itself (audits) is a powerful intervention. There are some possible other explanations than intervention for the observed change. Firstly, the self-collection of data may have resulted in attendance of those interested in CVDs and with a population of high CVD prevalence in the first audit. Secondly, due to the lack of a control group normal fluctuations in patient volumes could not be ruled out for certain. Attempts were made to control this bias by carrying out the audits at respective months. Thirdly, the introduction of EPR at the beginning of 2000's may have diminished the total number of appointments available. However, similar decrease was not seen in diabetes and dyslipideamia audits. Furthermore, similar trend for targeting services to those with poor treatment control was seen in diabetes audit and self-evaluations indicated that the resources were targeted at high-risk patients. The shorter duration of diabetes related intervention may explain the smaller effects

in diabetes audits [179]. The effects were opposite for the dyslipideamia audit and may indicate accelerated drug prescribing but there is no evidence on that.

The simple audits were used to allocate time needed for BP recordings and lifestyle counselling according to the guidelines. The allocations for BP measurements and counselling according to guidelines corresponded to the working hours of 66 nurses. In modelling studies in Norway, with maybe the healthiest population in Europe, it has been estimated that according to risk tools and guidelines the majority of the Norwegian adult population would be applicable for preventive activities and drug interventions [100, 231] with enormous demands for primary care. However, our modelling suggests, that by developing the process, task division and empowering patients, it is possible to target resources and release time resources to be rechanneled for other under-resourced actions. In this way it is possible to improve the value of health care for patients [263]. It is assumed the change did not impact negatively on the presumed quality of care perception of the patients', although the patients' perceptions were not surveyed. These simple methods accompanied with population data could help management to assess resource use, the needed resources and changes in needs. For these purposes diagnostic-related groups (DRG) have been used especially in hospital settings, but rarely in outpatient settings [102]. DRG was designed for cost control and has recently more and more been used in quality control and the planning of services. In DRG patients are grouped according to diagnoses and procedures, and health care services are defined as products. The key element, as in other register-based evaluations, is accurate recording and coding. Furthermore, in primary care the complex work content further hinders the use of such systems [161] but we do need tools to understand the actual work content of primary care. In Finland a diagnosis-related grouping has been modelled in primary care, and testing with a real budget is in progress (20).

6.4 Changing professional processes (III)

The use of diuretics for hypertension only patients was reduced opposite to the intervention aims while other changes in the main aims were concordant with the project aims. However, only a few statistically significant intragroup changes were detected and none in the intergroup comparisons. Three larger changes (increase of 5.2–7.1% units), presumably clinically significant, were detected; for the intervention group use of two or more concurrent drugs for diabetics and use of beta-blockers for CHD patients, and for the controls the use of RAAS for diabetics. The two latter changes seem to reflect poor baseline adherence while the change for diabetics in the intervention group may be intervention related. In rigorous RCT designs with interventions including individual feedback and focusing on prescribing the changes have been of similar magnitude ranging from -0.6 to +12% for the intervention

group with usually smaller concordant changes in the control group [88, 103, 212].

It seems, however, that professional barriers for change were not overcome, in the cases of prescribing knowledge and attitudes. One reason may be the topic, hypertension and other CVDs, major public health problems. GPs may feel that they are familiar with the treatment of these diseases and therefore do not recognize any need for change. It is possible that separate educational sessions for GPs accompanied with personal feedback on prescribing would have been needed to improve knowledge on prescribing recommendations, to show that there is room for improvement, and induce change [74, 254]. In addition presentation of preferred medication in flow charts would have facilitated change. Furthermore increase in the use of RAAS suggests that commercial intervention had stronger effects than our intervention. Environmental factors such as reimbursement practices and patients' perceptions may have hindered the change as well.

The prescribing outcomes were measured for facilitators who were the first line target group for implementation and were exposed to the most intense intervention. Since the change did not happen for the facilitators it is unlikely that the programme had any effect on GPs' prescribing more widely in the organisation.

6.5 Long-term effects of an intervention (IV)

No statistically significant differences in risk factors were detected at the end of the original intervention [157] nor at eight years post-randomisation and after six years of usual care. The main reason may be the contamination effect, the same GPs treated both the intervention and control groups and therefore the controls and other patients in the PCP benefited from the improved recognition of risk patients and more active treatement practices. However, the intervention patients were exposed to an intensive intervention and this possibly adapted their attitude toward CVDs. Therefore we wanted to study if the intervention had long-term effects. In the follow-up for both groups the decrease in diastolic BP was statistically significant and had an overall decreasing trend in BP compared to the baseline. Both groups had lower cholesterol levels. The chart audit showed further that risk factor levels were partly poorly recorded into patient records even for high-risk patients although the preventive actions should be targeted to these patients [289–291].

Similarly to our findings a systematic review on lifestyle interventions in a primary care setting found that the main effects of the interventions were on BP and cholesterol [78]. The authors defined effect sizes on BP as moderate if the P-value was under 0.05 and if compared with controls decrease in the mean systolic BP was 4–7 mmHg and for the diastolic BP 2–4 mmHg. In our study the difference in BP levels was 4.3/3.0 mmHg. And therefore, may be of clinical importance despite the fact that probably due to small sample size, it failed to show statistically significant

inter-group comparisons. Moreover these two risk factors are commonly modified with drugs. In lifestyle interventions enforced with drugs the main effect may come from medication. During the intervention over 50% used medication but only a few new patients with drug treatment were recognised in the follow-up. It seems that medication could not be realiably evaluated.

A number of randomised controlled trials have successfully demonstrated for moderate to high-risk patients the efficacy of intensive lifestyle interventions on cardiovascular risk reduction. The most known is possibly the Finnish Diabetes Prevention Study [266]. In addition to our previous study [158] only a few randomised controlled trials have used these intensive individualised interventions in primary care [70, 71, 121] and none to our knowledge had long-term follow-up results.

There are, however, a few long-term follow-ups (four to five years) in primary care with less intensive and individualised interventions targeted at moderate to high CVD risk patients [47, 69, 205]. In one of these studies yearly reinforcement of the intervention was offered but the attendance was low [69]. In a similar manner to our study, Cupples et al. found no statistically significant differences in risk factors after their intervention or after long-term follow-up [47, 48]. In the other two studies the improvements were sustained in some risk factors [69, 205]. What then maintains achieved improvements? According to Engberg et al. the reason is not medication [69] although in our case it is possible and maybe even probable. However, patients' more-positive attitudes and knowledge about prevention and lifestyle changes are possible factors as well [18].

7. CONCLUSIONS AND IMPLICATIONS

The present study addressed development of preventive work and guideline implementation in primary care at the local level as a means of internal facilitation. The special viewpoint was in organisational and individual professional processes, and structures. Furthermore at the patient level, long-term effects of an intensive intervention were studied. The specific conclusions and implications are the following.

Although the facilitators were committed to their role, the implementation of facilitation varied at the PCPs depending on facilitator activity. Nurses were more active in the intervention but pair facilitation enhanced the attendance and commitment of different professionals in QI. The personel reported changes in CVD prevention structures and processes; teamwork was strengthened by task division between GPs and nurses and clarified professional roles, and local guidelines were implemented in clinical practices. Additionally, patients were empowered with low cost structural changes (self measurement places). The possibility to be involved in changing working practices was rewarding, it gave the participants an increased sense of managing their own work and motivated them.

The outcomes for hypertension and diabetes patients, seen at appointments, worsened during the follow-up and improved for those with dyslipideamia. Therefore it seems that recognition of high-risk patients improved and the use of resources shifted towards those at high risk of CVDs and with poor treatment control. In the modelling, the working hours for BP measurements and lifestyle counselling for those with good or moderate treatment balance were halved while for those with poor balance it diminished by a third.

Changes towards guideline recommendations in individual practices, antihypertensive prescribing, were observed but they were parallel to the controls. More personalised interventions are needed to change prescribing practices. Our small sample for long-term effects of lifestyle interventions did not give solid evidence that individual patient-oriented interventions have long lasting effects.

To summarise the conclusions, it is possible to develop systematic preventive work practices in primary care with both structural and process-related changes. This enables the rechanneling of resources to those in poor treatment balance and allows the strengthening of basic task, prevention, of primary care towards value-based medicine.

Internal facilitation, with trained multiprofessional facilitators, offers the organisation solid and systematic structures for QI. Therefore consensus building, multiprofessional guideline implementation, and continuous evaluation with valid

performance measures should be encouraged more widely in primary care, especially in the near future when great changes are planned and implemented. Automatic data collection would further facilitate evaluation. Resource allocations, although they can only be approximations especially when surrogate measures are used, are valuable in planning services to meet the changing needs of population.

Sustainability of organisational QI structures, however, requires at the same time support, coordination and strong leadership. Incentives could be one way to support continuous QI in health care. Besides the development of processes, structural innovations, such as self-measurement sites, should be encouraged in primary care to offer low threshold means for patients to take more responsibility for their diseases.

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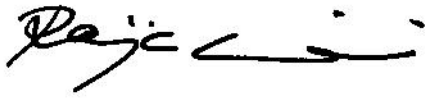

Raija Sipilä

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APPENDICES

Appendix I. Self-evaluation questionnaire (translated)

Profession: Doctor / Nurse / Other		
	Yes	**No**
1. Assessment of your own participation in the project (1–7; 1=not at all, 7 = a lot)		
2. Changes in task division and work content		
a) hypertension patients		
b) diabetes patients		
c) dyslipidaemia patients		
d) smokers		
3. I have used the Helsinki Prevention Programme materials from the intranet		
a) exercise prescription		
b) local guideline on elevated blood pressure		
c) local guideline on diabetes		
d) local guideline on dyslidaemia		
e) smoking cessation materials		
4. I use the Prochasca model in lifestyle counselling		
5. I direct patients to		
a) home measurements		
b) self-measurement sites		
6. My own evaluation on number of patients/week directed to self-measurement sites		
7. I have guided patients to use self-measurement sites		
8. Nurses extended permission to laboratory tests has been used		
9. Use of yearly controls for patients with		
a) hypertension patients		
b) diabetes patients		
c) patients with dyslipidaemia		

Appendix II. Instructions for conducting the blood pressure audit (translated).

A measurement for present situation for hypertension

All available nurses doing outpatient consultations perform one week's audit. Record

1. the total number of blood pressure measurements during the week (time period specified),
2. for each measurement for which blood pressure category it falls into
3. if you give lifestyle counselling related to hypertension, and
4. if the patient is referred to a doctor and the reason for the referral.

Instructions for the facilitators

Print one audit sheet for each auditor. Gather all results on one sheet, write down the health care unit, number of auditors and total number of nurses doing outpatient appointments in the unit.

Appendix III. The audit sheet for blood pressure (translated).

Audit for blood pressure (BP), 1 week									
Health care unit:									
Number of nurses attended to the audit / Total number of nurses in the unit									
Day	**Total number BP measurements**	**Number of patients with BP <140/85**	**Number of patients with BP 140-149/85-89**	**Number of patients with BP 150-160/90-95**	**Number of patients with BP >160/95**	**Lifestyle counselling, number of patients**	**Referred to doctors appointment**	**Reason for referral**
Mon								
Thu								
Wed								
Thu								
Fry								

Appendix IV. Contents of the individualised lifestyle intervention (IV)

Diet counselling, nurse: a 45-minute appointment with diet advice at the baseline and if needed at other scheduled intervention appointments. The advice was tailored according to individual patient's readiness to make lifestyle changes and to their risk factors. Advice was related to healthy eating: decreased intake of total fat and saturated fat, sodium, and alcohol, and increased intake of fibre. Calorie restriction was planned for the overweight. Patients were given written material.

Individual diet counselling, dietician (BMI≥35 kg/m^2): One meeting of 45-minute duration 3-day diet diary pre-counselling. The advice given was tailored according to the patients' readiness to make lifestyle changes and their risk factors. Advice was related to healthy eating: decreased intake of total fat and saturated fat, sodium, and alcohol, and increased intake of fibre. Calorie restriction was planned and a very low calorie diet (VLCD) could be used. In case of VLCD maximum 5 follow-up visits were scheduled. Patients were given written material.

Weight-reduction group: 8 meetings, duration á 1.5 hours, nurse leader. The programme consisted of short lectures, discussions and practical examples. The topics were: lifestyles and obesity, cardiovascular diseases, obesity and health, healthy diet, physical activity, and psycholocigal factors in weight reduction.

Tobacco cessation group: Four meetings, of 1.5-hour duration. The programme consisted of short lectures and discussions. The topics were: triggers for smoking, tobacco dependence, test for nicotine dependence, withdrawal symtoms, nicotine replacement therapy, plans for cessation, alternative sources of pleasure, and smoking and health.

Physical excercice programme, physiotherapist: Fifteen meetings, circuit training, of 45-minute duration . The training consisted of both aerobic endurance training and resistance training with individual goals. At the first meetings target levels were planned according to patient's baseline physical condition and disease history, and personal counselling on leasure time physical activity was given.